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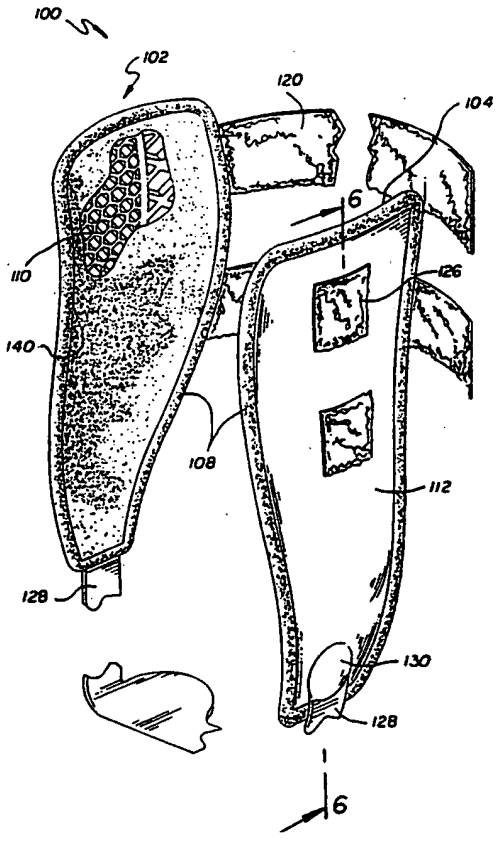
(57) Abstract

An ankle support (100) is constructed using a molded pad (110) and a rigid shell (112). The pad (110) and the shell (112) may be sealed together to form a bladder-pad cushion for comfort. The internal structure of the pad (110) is molded to include geometrically shaped cells of various size, shape and thickness to provide differing levels of localized comfort to the user of the ankle support (100). The pad may be made from a thermoplastic elastomer (TPE) which is spring-like and resists compression sets. The pad may include integrally-molded fingers extending to the shell. The fingers may have different lengths in one or more regions, in order to increase the cushioning effect in a particular region. The pad/shell combination may form a sealed bladder, and a pneumatic pump may be provided in conjunction with the shell so that the user can inflate the bladder.



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COMFORTABLE ORTHOPAEDIC SUPPORT

AND

THE METHOD OF MAKING THE SAME

Background of the Invention

Related Application

The present application is a continuation-in-part of U.S. Patent Application Serial No. 08/705,218, which was filed on August 29, 1996 and which is incorporated by reference herein.

Field of the Invention

The present invention generally relates to an improved orthopaedic device, and specifically to a orthopaedic support for body limbs or joints with emphasis on the construction of the support for comfort fit.

Description of Related Art

A variety of orthopaedic supports have been proposed to provide cushioned support to the limb, and most typically to an ankle and the lower leg after an injury. Typically, these ankle supports offer a rigid or a semi-rigid shell for sturdy support with padding for comfort. The padding material typically comprises foam, bladder, or other cushioning material. For example, in the U.S.

Patent 4,628,945, granted Dec. 16, 1986 to Glenn W. Johnson Jr., and entitled "Inflatable Ankle Brace with Porous Compressible Filler," an ankle brace comprising a rigid outer shell with an air-inflatable, bladder type liner is described. In that patent, the support is provided by the outer shells and the comfort is provided by the air-inflatable liner. Another design for an ankle brace is disclosed by the U.S. Patent 5,348,530 granted on September 20, 1994, also granted to Tracy E. Grim, William K. Arnold, and Joseph M. Iglesias and entitled "Pneumatic Ankle Brace with Bladder and Pump Arrangement." The '530 patent discloses an ankle brace design with rigid side supports and pneumatic bladder to serve as the cushioning material between the side supports and the wearer's leg.

Although these patents and others describe the padding materials used to improve the comfort to the person wearing the orthopaedic support, none of the previous designs suggest the provision in a single structure of different levels of support in different local regions of the limb being supported by the support.

U.S. Patent No. 5,366,439 to Peters discloses a pad made from several sheets of material, forming closed cells of pressurized air. The cells are all of uniform size and shape and do not provide specialized local support at distinct points on the ankle. The cells must be closed and filled with pressurized air, because otherwise the pad would not provide any support.

SUMMARY OF THE INVENTION

As an improvement over the prior designs, the present invention discloses a new design for supporting limbs. In this specification, the inventive design will be exemplified in ankle supports. The ankle support of the present invention provides for a creative way of forming and utilizing injection-molded resilient material, preferably thermoplastic elastomer (TPE) pads, to provide a light weight, durable padding while allowing for varying the degree of localized cushioning for different areas of the ankle support. Utilizing the injection molding technology, the resilient pads may be contoured and shaped to highly detailed designs. In addition to the varying the degree of localized support and cushioning, the orthopaedic support of the present invention may be used to provide the ideal levels of compression to the portions of the limb being supported.

An orthopaedic support for comfortably supporting a limb is disclosed in the present specification. As a typical application of the orthopaedic support, an ankle support will be discussed in this specification. The ankle support includes a outer shell formed for fitting about the limb, such as the lower leg, and a pad. A molded thermoplastic elastomer (TPE) pad is placed in between the outer shell and leg. The shell and the pad may be secured together by various means including infra-red welding, induction welding, bonding using adhesives, snap fitting, or overmolding. The pad is preferably made of molded TPE material and has molded structure to

provide differing levels of cushioning support for the wearer of the orthopaedic support.

The rigid shell of the ankle support may be formed to accommodate the malleolus or ankle bone when fitted on the user. Alternatively, the shell may be configured to surround but not cover the area around the malleolus. In that case, only the resilient padding may be configured to cover the malleolus.

The pad is welded on the shell or attached using other suitable methods. Alternatively, an overmold may be used to attach and may seal the resilient padding to the shell. The overmold may be of same material as the padding. If an overmold is used, the securing is accomplished by molding the overmold material at least around the edges of the ankle support. If the overmold material is the same material as the pad, then the overmold may be a mere extension of the pad and the boundary between the pad and the overmold may not be distinguishable.

Instead of using an overmold to seal the pad onto the shell, the pad, having at least one smooth, continuous side, may be welded directly onto the shell to seal the assembly.

A liner may be provided to cover the pad. The liner may be of a material such as cloth or other moisture absorbing material for more comfortable engagement with the skin of the user.

Typically, the TPE pad comprises a substantially continuous smooth side, and an opposing side with molded protrusions or cells. The TPE pad is then sealed to the

shell with the opposing side having the protrusions or cells facing the shell. If the seal is an air-tight seal, the shell-pad seal defines a bladder. Alternatively, the TPE pad itself may be configured as a bladder with cell structures built inside the bladder. This may be accomplished by placing a film of similar material on the open side of the cells and sealed around the outside to create a bladder, using the cells to prevent bottoming out during use. Alternatively, the molded pad provided with cells may be placed between two layers of air/fluid impervious film that are sealed around their periphery. In any case, the protrusions built within the interior of the TPE pad, which may be domes, cylinders, or other regularly or irregularly shaped protrusions, define the interior space of the ankle support and provides for differing levels of localized cushioning determined by the shape, size, and density of the protrusions, or cells, as well as the thickness of the walls of the cells. If the protrusions are shaped to define geometric areas such as rectangles, cylinders, etc., then each of the protrusions may be called a cell. The cell structure, defining the internal structure of the bladder, will be further discussed in the "Detail Description of the Preferred Embodiment(s)" section below.

To secure the orthopaedic support to the ankle and the lower leg, straps, buckles, or other suitable devices may be attached to the supports. Also, a heel strap, attached near the bottom of each of the ankle pads, connects the ankle supports to each other. The heel

straps are adjustable to fit the size of the wearer of the ankle support.

In accordance with one broad aspect of the invention, a pair of ankle supports for comfortably supporting the ankle are formed to conform to the shape of the ankle and the lower leg, and includes, for each of the supports, a shell and a resilient, preferably TPE pad for cushion. The pad includes molded geometric shaped cells within the pad to provide differing levels of localized cushioning.

In accordance with another broad aspect of the present invention, an orthopaedic support bladder pad is formed out of thermoplastic elastomer (TPE). The bladder pad is injection molded to include a space within its interior.

The space interior to the bladder pad may be filled with trapped air, or foam material, or geometric shaped cell structures made of the TPE material to provide differing levels of localized cushioning. The geometrically shaped cells may be interconnected via molded channels to allow air and/or fluid to pass between the cells.

The present invention also discloses a new method of manufacturing the comfortable ankle support. In accordance with a broad aspect of the present invention, the comfortable ankle support may be manufactured by forming a rigid shell for fitting about the lower leg, placing a resilient pad against the shell, and welding or otherwise bonding the resilient pad to the shell. The resilient material used for the padding is typically a

thermoplastic elastomer (TPE); however, the resilient material may be other than the TPE such as gels, thermoplastic urethane (tpu), thermoplastic rubber (tpr), two part urethanes, or foams, and the resilient material may be secured to the shell by overmolding with either a rubber or a plastic compound.

The orthopaedic support may include a heel bladder, connected to the side pads for providing varying pressures applied to the lower leg, as the patient walks.

In an alternative embodiment, the support may be provided with fingers that extend from the support to the ankle in order to provide cushioning to the ankle. The fingers may be of uniform length, or may have different lengths in different regions of the support. The fingers may be arranged at predetermined locations about the periphery of individual cells. The corresponding cells may be of different shapes in different regions. The length of the fingers and the shapes of the cells may be adjusted to customize the comfort and padding of the support in particular regions.

In a further alternative embodiment, the overmold may be molded about the edges of the shell rather than about the edges of the pad. The overmold may also be provided with a ridge that extends about the periphery of the overmold on the interior side of the shell, for bonding the pad onto the overmold.

Other aspects, features, and advantages of the present invention will be apparent to those persons having ordinary skill in the art to which the present

invention relates from the foregoing description and the accompanying drawings.

Brief Description of the Drawings

FIG. 1 is a diagrammatic, perspective view of a comfortable orthopaedic support as exemplified by comfortable ankle supports illustrating the present invention;

FIG. 2 is an exploded view of the ankle support shown in FIG. 1, and illustrating the construction of the ankle support;

FIG. 3 is a perspective detailed view of the internal cell structure of the thermoplastic elastomer (TPE) pad illustrated by FIG. 2;

FIG. 4 illustrates various internal geometric shaped cells and channels of the TPE pad;

FIG. 5 is a partial transverse cross-sectional view of the pad shown in FIG. 4 taken along lines 5-5 of FIG. 4.

FIG. 6 is a cross-sectional side view illustrating the structure of one alternative embodiment of the ankle support shown in FIG. 1, taken along lines 6-6 of FIG. 1;

FIG. 7 is an cross-sectional side view of an alternative embodiment of an ankle support;

FIG. 8 illustrates the areas of the ankle support which may require differing levels of cushioning and support;

FIG. 9 is a diagrammatic, perspective view of an alternative embodiment of the ankle support of the present invention employing foam material for cushioning;

FIG. 10 is a cross-sectional side view illustrating the ankle support pad structure, taken along lines 10-10 of FIG. 9;

FIG. 11 is a cross-sectional side view illustrating the ankle support pad structure of an alternative embodiment;

FIG. 12 illustrates an alternative embodiment of the shell with a removable core for varying the rigidity of the shell;

FIG. 13 illustrates an alternative embodiment of the ankle support and pad in which a channeled pad is employed;

FIG. 14 illustrates inlet and outlet ports and valves of an ankle support useful for hot and/or cold therapy; and

FIG. 15 is a cross-sectional view of another embodiment of the present invention;

FIG. 16 is a rear elevational view of the exterior of an alternative embodiment of a pad according to the present invention;

FIG. 17 is a cross-sectional view taken across line 17-17 of Fig. 16;

FIG. 18 is a cross-sectional view taken across line 18-18 of Fig. 16;

FIG. 19 is a detail perspective view of an interior portion of the pad of Fig. 16;

FIG. 20 is a perspective view of a shell to which the pad of Fig. 16 is to be bonded; and

FIG. 21 is a cross-sectional view taken along line 21-21 of Fig. 20 illustrating the overmold that is molded about the edges of the shell itself.

Detailed Description of the Preferred Embodiment(s)

Referring to the drawings, particularly to FIG. 1, a comfortable orthopaedic support 100 is shown. As a preferred embodiment of the present invention, and to facilitate the description of the present invention, this section of the document will discuss comfortable ankle supports. However, comfortable orthopaedic supports in accordance with the present invention may be manufactured for and applied to other parts of the body.

FIG. 1 illustrates an ankle brace including an ankle support 102 for the medial side of the lower leg and a cooperative ankle support 104 for the lateral side of the lower leg. However, because the ankle support design of the present invention is applicable for either one or both sides of the lower leg, the following discussions will not differentiate between the medial and the lateral side supports. The ankle support comprises a rigid outer support, or a shell, 112, and a thermoplastic elastomer (TPE) pad 110. The shell 112 and the pad 110 may be welded together or may be sealed together by an overmold 108 at least around the edges. The overmold 108 may be an extension of the TPE pad 110 and made of the same TPE material as the pad 110. A flexible layer 140 is preferably integral with pad 110, but may be separate and bonded thereto. The rigid side support 112 may be shaped to accommodate the ankle or the malleolus area. The TPE

pad 110 has an inner structure as shown by the cut-away area to various geometric shapes to provide differing levels of localized comfort. The interior design of the pad 110 will be further illustrated by the following figures and the corresponding discussions below. A heel strap 128 is attached to the lower portions of both of the ankle supports by a cap 130.

The comfortable ankle support may be secured onto the lower leg using fastening fabric, such as the hook and loop type fastening material sold under the trade name VELCRO®, straps and buckles, or any other suitable means. FIG. 1 illustrates the use of the loop-type VELCRO® straps 120 along with the hook-type VELCRO® sections 126 attached to the shell 112 as the means of securing the ankle supports to the lower leg.

Although the preferred embodiment of the present invention as disclosed as being implemented using a pair of rigid side supports, the pad 110 may be used as the cushioning member for a unitary ankle support such as the "Adjustable Tension Ankle Support" disclosed by U.S. Patent No. 4,869,267 issued to Tracy E. Grim and Thomas M. Smario.

FIG. 2 is an exploded view of an ankle support illustrating the construction of the ankle support and its internal structure. Incidentally, Fig. 2 is shown flat for convenience and clarity in showing the internal construction, but would actually be curved and contoured to the general shape of the ankle as shown in Fig. 1. Figs. 3, 4, 8 and 12 have also been illustrated as being flat, but would actually be curved in configuration.

Returning to Fig. 2, the shell 112a as illustrated may be partially covered by the TPE material 142 which may be an extension of the overmold 108a which may also cover the TPE pad 110a. The pad 110a is placed in between the outer support, or rigid shell, 112a and the inner liner 140a. The liner 140a may be of same TPE material as the pad 110a or other suitable materials such as cloth, neoprene, etc. Alternatively, the liner 140a may not be necessary if the pad 110a has a substantially continuous skin on the side of the pad upon which the liner is expected to attach to. The overmold 108a may comprise the resilient material which seals the shell 112a to the pad 110a. The inner cell structure of the TPE pad will be illustrated in detail by FIGS. 3 and 4 and described by the corresponding discussions below. If the pad 110a is welded to the shell 112a, the overmold 108a may not be a necessary element of the ankle support.

The rigid outer support, or the shell, 112a may be formed of relatively stiff or semi-rigid plastic, and may include cutouts 144 and 146 which serve to increase the shell's flexibility near the malleolus area 145 to increase the comfort and to decrease the chance of the shell 112a digging into the often sensitive ankle region. The cutouts 144, 146 may be implemented on any portion of the shell 112a to increase the flexibility of the shell 112a for the area. A receptacle 148 is provided near the bottom of the shell 112a to allow the attachment of the heel strap 128 of FIG. 1 by welding, snap-fit with a retention cap, rivet, or other suitable attaching means.

The liner 140a of the ankle support is substantially smooth. The overmold 108a as utilized substantially covers at least the outer edges of the TPE pad 110a, the liner 140a, and the shell 112a forming an air-tight seal and trapping air.

Again, if the pad 110a is welded or bonded onto the shell 112a and if the pad 110a includes a substantially continuous surface (for the side away from the shell), then the liner 140a and the overmold 108a are not necessary elements of the ankle support.

In the embodiment as shown by FIG. 2, the shell 112a surrounds but does not cover the malleolus or protruding portion of the ankle, allowing the malleolus to extend into the ankle support. That area is covered only by the outer surface of the TPE pad 110a or the liner 140a.

In an alternative embodiment, the shell itself includes the overmold about its edges. A pad is molded separately, and the edge of the pad is bonded to the overmold The liner 140a would either be molded with the lip, or would be a separate material onto which the lip 108a is molded.

FIG. 3 provides a detailed perspective view of the interior design of the TPE pad 110a. The TPE pad 110a is injection molded to include various protrusions or cells. These cells may be molded as domes, pyramidal or other regularly or irregularly shaped geometrical protrusions. The embodiment as illustrated by FIG. 3 includes various sized hexagonal cells resembling honeycomb structures 152 and 154, cylindrical cells 156, criss-cross or checkered-patterned cells 160, and irregularly shaped cells 158.

The size, shape, and density of the cells as well as the thickness of the walls defining the cells determine the level of cushioning for the local areas of the ankle support.

The utilization of the injection molded TPE material for orthopaedic supports has many advantages. First, the TPE pad can be molded to include detailed designs such as geometrically shaped cells. The TPE pad can be specifically contoured to the malleolus areas, the calf, and the calcaneal regions of the support. Although the TPE material is more dense than other padding materials such as foam, the innovative design including molded cell-structure as illustrated by FIGS. 2-7 overcomes this disadvantage by reducing the weight of the product. The reduction in the weight of the pad also translates into lower cost and increased value to the end user of the product.

One suitable thermoplastic elastomer (TPE), is available under the name RIMFLEX, made from KRATON® Polymer. It is produced by Shell Oil Company and is available from Synthetic Rubber Technologies of Uniontown, Ohio. There re many other sources of thermoplastic elastomers. The material may be molded by any of the numerous injection-molding companies across the nation. Other material may be used in place of the TPE, including thermosetting and thermoplastic materials.

Continuing to refer to FIG. 3 but also referring to FIG. 4, the geometrically shaped cells of the pad 110 may be interconnected via channels 162 and 164 as illustrated by FIG. 4. The figure illustrates channels 162, molded

between the cells of the TPE pad 110a to allow passage of air or fluids amount the cells of the pad 110a. The channels provide the means for the movement of the air or fluids between the cells, creating a massaging effect on the lower leg, thereby promoting blood flow. Also, the channels may be designed in a manner in which external fluid may be circulated with the ankle pad for hot and cold therapies.

FIG. 4 also illustrates the fact that the cells of the pad 110a may be molded to include shapes such as logos and trademarks as well as geometrical shapes as indicated by reference number 165.

FIG. 5 is a partial transverse cross-sectional view of the TPE pad embodiment as shown in FIG. 4 taken along the line 5-5. The geometric cells 111 are defined by its walls 113. In the embodiment as shown, the pad 110a includes a smooth, substantially continuous side 110b eliminating the need for a liner 140 of FIG. 2 for this embodiment. However, even though not required, a liner 140b still may be used to increase comfort.

FIGS. 4 and 5 also illustrate that the cells of the pad 110a may include openings 163 on its smooth side allowing air to pass in and out of the pad to relieve pressure. If the liner 140b is made of cloth or other breathable material, the openings 163 do not have to extend through the liner 140b.

Referring now to FIGS. 6 and 7, cross-sectional side views illustrating the internal structure of the ankle supports of FIG. 1 are illustrated. Referring specifically to FIG. 6, a cross-sectional side view of

the ankle support is illustrated. The shell 112 provides rigid or semi-rigid support for the ankle support and the TPE pad 110 provides the cushioning for the ankle support. The TPE pad 110 includes geometrically shaped cell structures. The overmold 108 may seal the TPE pad 110 and the liner 140 to the shell 112. If the seal is an air-tight seal, and the liner 140 (which is an integral part of the pad 110) includes no openings as illustrated by the reference number 163 of FIG. 4, then a bladder is formed. In the embodiment as shown, the shell 112 covers the entire lower leg including the malleolar area. Also, the TPE pad 110 may include a smaller, internal bladder 172 around the malleolus area providing additional level of cushioning. Alternatively, instead of a bladder 172, the additional cushioning may be provided by inserting other soft material in the space such as open cell foam material or gels.

Reference number 117 shows that the structures for the pad 110 may be formed such that the TPE material does not span the entire distance from the liner 140 to the shell 112 creating a pressure free travel of the padding 110 to the shell 112. The pressure free travel design provides for unsurpassed softness and comfort for the area of the pad. This technique allows additional air to be trapped under the pad 110 and creates additional room for the pad 110 to flex for softer cushioning. Also, the reduction in the amount of material used for the pad 110 leads to a lighter ankle support and reduced production costs.

An alternative embodiment of the ankle support is illustrated by FIG. 7. Similar to the ankle support as shown by FIG. 6, the shell 112c and the TPE pad 110c are sealed to each other by an overmold 108c substantially molding at least the edges of the shell 112c and the pad 110c. However, unlike the embodiment of FIG. 6, the pad 110c of FIG. 7 does not include internal geometric structures for cushioning. The pad 110c includes only an internal bladder 172c around the malleolus area.

In the embodiment of the present invention as illustrated by FIG. 7, the cushioning is provided by internal structures molded directly onto the shell 112c as illustrated by reference number 119. In this embodiment, the cell structures for the padding, such as the geometric configurations shown in other figures, has been initially molded directly on the shell 112c. Subsequently, the layer 108c is bonded to the shell 112c around the edges of the shell, leaving the open spaces defined by the molded cell structures 119.

Utilizing the geometrically shaped cells molded onto the TPE pad, the ankle supports 102, 104 of FIG. 1 may provide differing levels of cushioning to the different areas of the lower leg being protected by the ankle support. FIG. 8 illustrates one possible map of the areas of the ankle support which may require different levels of cushioning. For instance, the malleolus area 188 may require very soft support using a configuration indicated by reference number 117 of FIG. 6 or could be provided by an internal bladder-type structure 172c as shown in FIG. 7. Using the construction shown at 117 in

Fig. 6 would allow some distance for free travel, with increasing resistance, and protection against bottoming out. The area 186 surrounding the malleolus may require a soft cushioning, slightly firmer than the area 188, to avoid aggravation of an injured malleolus. The area 184 supporting the lower tibia may require firm support and its surrounding area 182 may require softer cushioning for comfort. The softer cushioning around the edges of the support prevents the edges of the shell from digging into the wearer's leg. As already indicated, the degree of cushioning of these areas may be predetermined. Other mapping schemes may be used to support the ankle region or to support other limbs of the body.

An alternative embodiment of the orthopaedic support 200 is illustrated by FIG. 9. The ankle supports 202 and 204 of this embodiment of the orthopaedic support 200 include other cushioning materials in addition to TPE pads as described above. The additional cushioning may be provided by the embedded cushioning material 212. Typically, the material used for the embedded cushioning is foam or gels. Because the TPE material is more durable (tear-resistant), flexible, water resistant, and hypo-allergenic than foam material, it makes a better padding for ankle supports. However, because of its higher density, it may not provide cushioning which is as soft as may be desired, and could involve some increase in weight. Using the design illustrated by FIG. 9, the benefits of the TPE pad may be retained while gaining the additional cushioning and reduction in weight, provided by the foam core 212.

In short, FIGS. 1-8 illustrate an embodiment of the ankle support of the present invention where the padding for the support is created using injection molded TPE pads with internal geometrically shaped cells. Alternatively, FIGS. 9-11 illustrate an embodiment of the ankle support of the present invention where the padding for the support is created using a molded TPE pad with a cushioning core of a different material.

Also illustrated by FIG. 9 is the adjustable heel strap 228 which may be detachably mounted to the ankle supports using the loop and hook type mounting member 236 which, in turn can be affixed to the lower portion of the ankle supports permanently or by a snap-on unit or other suitable attaching means.

The shell 112d of the ankle support 202, 204 may be formed to surround but not cover the malleolus area 114d, with the trampoline cushioning effect resulting from the lack of rigid coverage in the malleolus area allowing less padding in that area.

Referring to FIGS. 10 and 11, cross-sectional side views illustrating the ankle support pad structure, taken along lines 10-10 of FIG. 9 is shown. The foam pad 212 is embedded in the TPE pad 110d between the shell 112d and the outer surface 140d of the TPE pad 110d. This construction increases the cushioning of the TPE pad 110d while maintaining the water resistance, durability, and other favorable characteristics of the TPE pad.

Alternatively, for the cross section of the ankle support as illustrated by FIG. 11, the embedded foam pad 212a, 212b does not cover the malleolus area. Rather,

the foam pad surrounds the malleolus area as indicated by 212a and 212b. As illustrated by FIG. 11, only a layer of the TPE pad 110d covers the malleolus area. This creates a "trampoline" type effect. The malleolus, as illustrated by the figure, is covered by a TPE "trampoline," which provides a flexible padding without the rigid shell. The foam pad 212a and 212b of may be replaced by gel because, unlike the design illustrated by FIG. 10, the space defined 212a and 212b is completely enclosed by the TPE over pad 110d.

FIG. 12 illustrates an adjustable shell design applicable to the present type of ankle support. The shell 112e may comprise a rigid or semi-rigid plastic shell frame 220 and a shell core 222 which may be removable. The removable shell core 222 may be replaced with more or less rigid shell cores as the needs of the patient change over time. The initial shell core 222 may be of a very rigid material so that prevention of inversion or eversion is greatest, thereby allowing the patient to regain stability in his or her ankle. Once the ankle has healed and the patient is ready for more demanding forms of exercise, the shell core 222 may be changed to a less rigid material so as to allow further movements of the ankle. Further, the shell core 222 may be removed entirely for further flexion, if desired. In the embodiment as illustrated by FIG. 12, the shell core 222 fits snugly into the shell frame 220, and snaps into place. The snapping action is accomplished using a protrusion 224 and the indentation 226.

The arrangement of Fig. 12 can also be employed as a "trainer" style ankle support to prevent injury to an ankle that has healed somewhat but which requires protection from reinjury. In the "trainer" embodiment, the outer shell 220 is made from a flexible material such as a low density polyethylene or polypropylene. An insert 222 may be made from a material that is more rigid than the flexible outer shell 220, such as high density polyethylene, steel, nylon and other rigid materials.

In the preferred embodiment that Fig. 12 illustrates, the insert 222 snaps into place on the shell 220. However, the insert may alternatively be secured to the shell 220 in other ways, such by rivetting, with adhesive, or by welding into place. An advatage of this arrangement is that the insert 222 may be secured into place immediately after the ankle is injured. However, after the ankle has healed somewhat, the insert 222 may be removed from the outer shell 220, making the support more flexible and allowing the person wearing the support to engage in a wider variety of activities.

Yet another alternative embodiment of the ankle support is illustrated by FIGS. 13 and 14. Referring to FIG. 13, the ankle support 230 is illustrated with a shell 112f and the TPE pad 110f with molded tubular channels 240 and grooves 241 as its inner surface. Such design is particularly useful for hot and cold treatments of the ankle and the lower leg. FIG. 14 illustrates a water intake port 242 and an intake valve 244 and a water outlet port and an outlet valve 248.

Another alternative embodiment of the orthopaedic support of the present invention is illustrated by FIG. 15. The heel member 250 comprises a bladder 252 linked via channels 254, 256 to the ankle supports which has its TPE pads 110g configured as bladders as well. Each time the foot of the wearer presses down on the heel member 250, the air or the fluid within the bladder 252 is pressured into the bladder-pad 110g of the ankle supports thereby massaging the lower leg. The pads or bladders 110g may be as shown in earlier figures of the drawing, and may have channels 163a interconnecting the cells of the pads. The channels 254, 256 may be formed integrally with the heel bladder 252, or separate air channels or tubes may be provided to interconnect the heel bladder 252 with the side pads 110g.

Figs. 16-20 illustrate a further alternative embodiment of the present invention. In this embodiment, the support is provided with a plurality of thin "fingers" 321, which are most clearly seen in Figs. 17 and 18. The fingers 321 are molded about the periphery of the respective honeycomb cells 352 and 353. The fingers extend from the molded interior elastomer pad 310 of the support to the hard outer plastic shell 312 (Fig. 20). The entire interior elastomer pad 310, which has an edge 310a, can be molded in a single injection molding step to simplify manufacturing.

The aspect ratio of the fingers 321 are varied to provide more or less cushioning in particular regions of the support. For example, Figure 18 illustrates the

change in finger heights in different regions of the pad, including longer fingers 321a and shorter fingers 321b. In much of the support, the fingers 321b are relatively short with respect to the diameter of the fingers. On the other hand, the fingers 321a are considerably longer than the fingers 321b in the rest of the pad. Consequently, the area or areas of the support having the longer fingers 321a will provide more cushioning than the areas of the support having the shorter fingers 321b. That is, the longer fingers 321a flex more than the shorter fingers 321b in response to pressure on the support from the ankle.

The fingers 321a,b also serve to space the flexible inner portion of the support from the hard outer portion of the support. Consequently, the longer fingers 321a provide additional space between the malleous of the ankle and the hard outer shell 312 of the brace. The malleolar region of the ankle is typically where the ankle is injured, and the injury may be exacerbated if the injured portion of the ankle hits the hard outer shell of the support. The longer fingers prevent the malleous from hitting the hard outer shell during use, and provide softer cushioning which makes the brace more comfortable for the wearer during healing.

It should be noted that the outer shell 312 in Fig. 20 includes air holes 315a that allow air within the support to ventilate in and out. In this embodiment of the invention, the cells support the ankle without the need for pressurized air. That is, the structure of the cells themselves rather than pressurized air provide the

support for the ankle. This is in contrast to pressurized-air types of supports, which do not provide cushioning unless the support is inflated prior to use.

Additional air holes 355 may be included in the pad 310 itself. For example, the pad 310 in Fig. 16 has numerous air holes in both the bottom and top portions of the pad. Consequently, air is free to flow in and out of the spaces between the pad and the shell. This may be advantageous in, for example, high altitude locations where the air pressure in an air-filled bladder relative to the ambient pressure may become greater than desirable. The present embodiment of the pad, which does not inflate with air, therefore does not have a problem with air pressure in high altitudes.

As an additional alternative, the thickness of the pad walls may vary in different regions of the pad. For example, the wall thickness of the pad of Fig. 18 is greater in the lower region of the pad 357 than in rest of the pad 359. This is because the lower region of the pad generally corresponds to the area of the ankle that is injured and where there is swelling. Increasing the thickness of the skin causes the pad to feel firmer, and decreasing the thickness makes the pad feel softer.

A pad having varying skin thickness is preferably formed by injection molding. However, other methods in which a liquid material solidifies to form to the shape of the mold, such as (for example) reaction-injection molding or pour molding may be employed. To vary the thickness of the skin of the pad while at the same time forming a pad cell structure and integral fingers

generally requires a manufacturing method in which a liquid material fills a cavity defining the desired pad configuration, then solidifying to conform the shape of the pad to the shape of the cavity.

Referring in particular to Figs. 20 and 21, the shell 312 is provided with an overmold 308 that extends about the periphery of the shell. The overmold is typically formed of the same material as the pad 310, so that the pad can be easily bonded to the overmold. The overmold 308 has a ridge 309 about which the outer edge 310a of the pad extends when the pad is bonded to the overmold. The fingers 321 extend from the pad 310 to the shell 312, with the outer surface of the pad 310 being substantially continuous.

In the presently preferred embodiment, the pad 310 bonds only to the overmold 308 to secure the pad to the shell. The pad is typically bonded to the overmold with a conventional solvent that melts material on both the edge 310a of the pad and on the overmold. The melted material then solidifies to form the bond. However, the pad may be bonded to the overmold in other ways, such as by welding or with adhesives. In alternative embodiments, the pad may be adhered directly to the shell.

In the preferred embodiment of the present invention as illustrated by FIGS. 1-15, a comfortable orthopaedic support is implemented with ankle supports and a heel strap. The ankle supports comprise a rigid shell and padding made from molded thermoplastic elastomer (TPE) with or without other padding material. The TPE pad may

be sealed to the shell with trapped air or fluid between the pad and the shell to form a bladder. A lining material may cover the pad. To provide localized comfort, the TPE pad may be molded to include various protrusions or cells toward the shell. These cells may be shaped as domes or other geometric shapes such as honeycomb shapes. Alternatively, soft foam may be embedded between the rigid shell and the durable TPE padding to provide durable surface with soft padding. Another option is to use gel in place of the soft foam or the molded TPE pad. Typically, the overmold which seals the TPE pad to the shell is made of same TPE material as the padding and also partially covers the shell.

Although the present invention has been described in detail with regarding the exemplary embodiments and drawings thereof and with regarding alternate embodiments, it should be apparent to those skilled in the art that various adaptations and modifications of the present invention may be accomplished without departing from the spirit and the scope of the invention. Thus, by way of example and not of limitation, the present invention has been described as an ankle support. However, it is apparent that the inventive support may be applied to arms, legs, and other part of the body requiring varying degrees of localized comfort. Incidentally, where reference is made hereto to air cells or geometric cells, reference is to macro-cells with dimensions greater than 1/64 or 1/32 of an inch for example, and not to foams. Accordingly, the invention is

not limited to the precise embodiment shown in the drawings and described in detail hereinabove.

Pads according to some of the embodiments of the present invention may be sealed, such that a space is formed between the pad and the shell that can be filled with air or other fluid to form a fluid bladder. The shell may include an air pump with which the user can inflate the bladder. A release valve can be provided permitting the user to release air from the bladder as necessary.

It should be noted that the cell structure described in connection with the present invention has additional applications. For example, open cells can be inserted in between two layers of material which together form a bladder. The cells act as reinforcement to the bladder, such that if the bladder deflates or if an especially great load is applied to the bladder, the cell structure reduce the likelihood that the bladder will bottom out.

While a pad made with a TPE material has been described, and while the inventors presently prefer to make the pad from TPE material, it should be understood that the pad may be made from a variety of other materials. For example (but without limitation) the pad may be made of thermoplastic urethanes, thermoplastic rubbers, silicones, two-part urethane mixtures and poured foams.

It should be noted that the fingers 321 are shown in the figures as having a generally circular cross-section. However, the fingers can have various other cross-sections, so long as they perform a cushioning function.

While the pads described herein are particularly well suited for use in orthopaedic supports, there are numerous other applications in which such pads could be employed. For example, embodiments of this type of pad may be employed in various protective devices, such as knee pads, shin guards, and football pads, among other applications where durability and water resistance are desired.

From the foregoing detailed description, it will be evident that there are a number of changes, adaptations, and modifications of the present invention which come within the province of those skilled in the art. However, it is intended that all such variations not departing from the spirit of the invention be considered as within the scope thereof as limited solely by the claims appended hereto. It is therefore intended that the following claims may be interpreted as covering all such applications, alterations and modifications as fall within the true spirit and scope of the invention.

CLAIMS

WE CLAIM:

1. An orthopaedic support for comfortably supporting the ankle of a wearer, comprising:

an outer shell formed for fitting about the lower leg of the wearer;

a molded pad bonded to said shell;

said pad having a surface; and

said pad having a plurality of molded structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, at least some of said structures having a different dimension than others of said structures.

2. An orthopaedic support in accordance with 1 wherein an overmold substantially surrounds said pad and said shell substantially sealing together said orthopaedic support.

3. An orthopedic support as defined in claim 1 further comprising an overmold molded onto said shell, said pad being bonded to said overmold.

4. An orthopaedic support as defined in claim 1 further comprising means for securing said ankle support around the lower leg; and a heel strap for securing said orthopaedic support.

5. An orthopaedic support as defined in claim 1 wherein said pad bonded to said shell forms a fluid-filled bladder.

6. An orthopaedic support as defined in claim 1 wherein an inner liner of cloth is secured to said pad on the surface of said pad facing the lower leg of the user.

7. An orthopaedic support as defined in claim 6 wherein said liner is integrated with said pad.

8. An orthopaedic support in accordance with claim 7 wherein said liner includes openings allowing air to pass in and out of said structures.

9. An orthopaedic support as defined in claim 1, wherein said pad further comprises a plurality of fingers extending from said pad to said outer shell.

10. An orthopaedic support as defined in claim 9, wherein said fingers are integrally molded with said pad.

11. An orthopaedic support as defined in claim 9, wherein some of said fingers have a different length than others of said fingers.

12. An orthopaedic support as defined in claim 11, wherein said support has a malleolar region that is adapted to be placed against a malleolus of an ankle, said malleolar region having fingers of a greater length than fingers in other regions of said support.

13. An orthopaedic support for comfortably supporting a select area of the anatomy, said support comprising:

a substantially rigid shell; and

an injection molded resilient pad between said shell and the anatomy of the user, said pad configured with geometric shaped cells providing cushioning and support.

14. An orthopaedic support as defined in claim 13 further comprising an overmold molded onto said shell, said pad being connected to said overmold.

15. An orthopaedic support as defined in claim 13 wherein said pad is a bladder having a plurality of cells having cushioning geometric shapes and protrusions, each cell with predetermined size, depth, and wall thickness providing varying levels of localized support and cushion in different areas of said support.

16. An orthopaedic support as defined in claim 15 wherein said geometric shapes for said bladder are selected from the group consisting of ribs, cylinders, honeycomb, and regular and irregular polygons.

17. An orthopaedic support as defined in claim 15 wherein channels are provided between said cells for allowing a fluid to pass between and among said cells, creating a massaging effect on the ankle and promoting blood flow.

18. An orthopaedic support as defined in claim 17 wherein channels are provided through an outer wall of said pad to at least one of said cells to allow water to pass between and among said cells for hot and cold therapies.

19. An orthopaedic support as defined in claim 17 wherein said support further comprises inlet and outlet valves for allowing entry and removal of air and liquids.

20. An orthopaedic support as defined in claim 13 wherein said pad further comprises a foam core for softer inner cushion.

21. An orthopaedic support as defined in claim 13 wherein a co-molded lip around said shell and around said pad seals said pad such that air is trapped between said pad and said shell, creating a bladder with air cushion.

22. An orthopaedic support as defined in claim 13 wherein said pad is molded directly onto said shell as channels, domes, and other supportive geometrical shapes to cushion and to support the anatomy.

23. An orthopadic support as defined in claim 13 wherein said pad includes a plurality of fingers extending from said pad to said shell.

24. An orthopaedic support comprising:

a substantially rigid shell formed to fit a limb of a user;

an injection molded pad for cushioning the shell to the limb;

said injection molded pad being integrally molded in a single molding step.

25. An orthopaedic support as defined in claim 24 wherein said pad includes interconnected cells, and further comprising a heel bladder fluidically coupled to said pad for varying the pressure exerted by said pad on the limb of the user.

26. An orthopaedic support pad as defined in claim 24 wherein said pad is a bladder having geometrically shaped cells to provide differing levels of localized cushioning and a plurality of channels molded between said cells to allow air and fluid to pass between said cells.

27. An orthopaedic support pad as defined in claim 26 further comprising fluid inlets and outlets to allow entry and removal of fluid from said pad for hot and cold therapy.

28. An orthopaedic support as defined in claim 26 wherein at least one cell defines a closed space forming an internal bladder.

29. An orthopaedic support as defined in claim 24 wherein said shell further comprises a shell frame and a shell core which is removably mounted within said shell.

30. An orthopaedic support as defined in claim 24 wherein a breathable liner covers said pad.

31. An orthopadic support as defined in claim 24 wherein said pad includes a plurality of integrally-molded fingers extending from said pad to said shell.

32. An orthopaedic support as defined in claim 24 further comprising an overmold molded onto said shell.

33. An orthopaedic support for comfortably supporting the ankle comprising:

an ankle support formed for fitting about the lower leg, having appropriate configuration to support the ankle;

said ankle support comprising a substantially rigid outer shell and a molded pad for cushioning;

said pad having an inner surface and an outer layer, said inner surface including resilient material having cells therein for providing resilient support to the ankle; and

said pad being bonded to said outer shell;

wherein said outer shell has at least one opening to allow air to escape from space in between said outer shell and said pad, said cells providing resilient support to the ankle from the structure of the cells even without being filled with air.

34. An orthopaedic support as defined in claim 33 wherein at least some of said air spaces are filled with foam for cushioning.

35. An orthopaedic support as defined in claim 34 wherein said foam surrounds but not covers the malleolus.

36. An orthopaedic support as defined in claim 33 wherein said pad includes a plurality of fingers extending from said pad toward said shell.

37. An orthopaedic support as defined in claim 33 further comprising an overmold molded onto said shell.

38. An orthopaedic support as defined in claim 37 wherein said pad is bonded to said overmold.

39. An orthopaedic support as defined in claim 38 wherein said overmold includes a ridge extending about the periphery of the overmold, said pad having an outer edge that engages with said ridge.

40. An orthopaedic support as defined in claim 33 wherein said pad includes a plurality of air holes to prevent formation of a bladder between said pad and said shell.

41. An orthopaedic support as defined in claim 33 wherein said pad has a non-uniform skin thickness, said pad having at least one region having skin that is thicker than at least one other region, in order to improve the function of the support.

42. An orthopaedic support comprising:

a flexible, molded outer shell having a first surface and a second surface, said first surface having an indentation therein; and at least one insert comprising a material that is relatively stiffer than said outer shell;

said support having a first mode in which said insert is removably secured within said indentation to stiffen the support, and a second mode in which said insert is removed from said indentation to make said support more flexible relative to said first mode.

43. An orthopaedic support as defined in claim 42, wherein said insert and said outer shell are adapted such that said insert is securable into the indentation in said outer shell by snap fit.

44. An orthopaedic support as defined in claim 42 further comprising a molded pad bonded to said shell, said pad having a substantially continuous surface and having a plurality of molded structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, said substantially continuous surface of said pad being adapted to be placed against a portion of the

anatomy to be supported.

45. An orthopaedic support comprising:

a flexible, molded outer shell; and

at least one auxilliary member comprising a material that is relatively stiffer than said outer shell;

said support having a first mode in which said auxilliary member is removably secured to said outer shell to stiffen the support, and a second mode in which said insert is removed from said support to make said support more flexible relative to said first mode.

46. An orthopaedic support as defined in claim 45 further comprising a plurality of different interchangeable auxilliary members, each having a different stiffness, wherein a user may select a particular member depending on the stiffness desired.

47. An orthopaedic support for comfortably supporting the ankle of a wearer, comprising:

an outer shell formed for fitting about the lower leg of the wearer;

a molded pad bonded to said shell;

said pad having a plurality of molded structures in between said pad and said shell to provide cushioning support for the wearer.

48. An orthopaedic support for comfortably supporting a select area of the anatomy, said support comprising:

a substantially rigid shell; and

an injection molded resilient pad between said shell and the anatomy of the user, said pad being configured with geometric shaped cells providing cushioning and support;

said pad being bonded to said shell to form a fluid-filled bladder.

FIG. 1

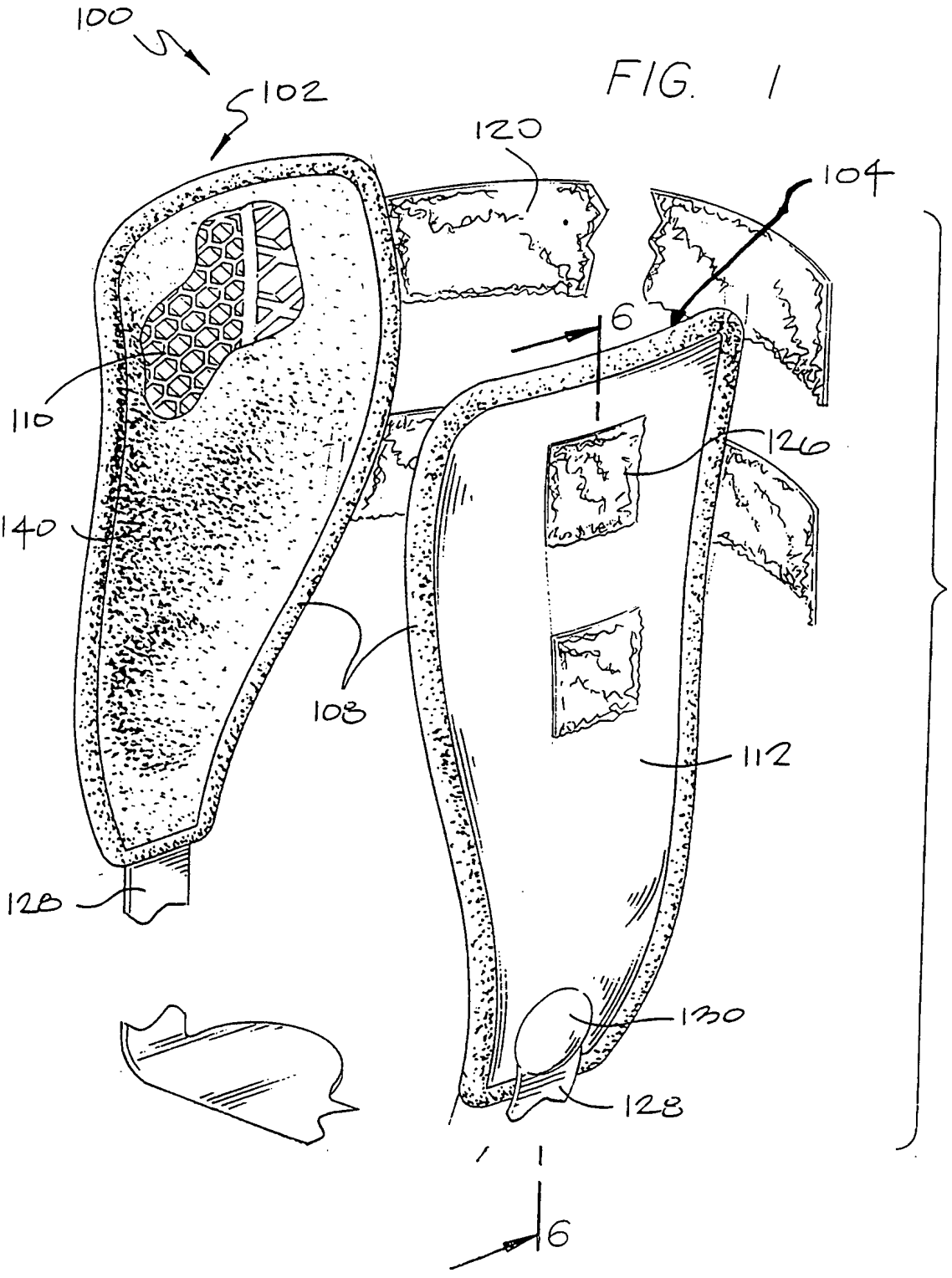
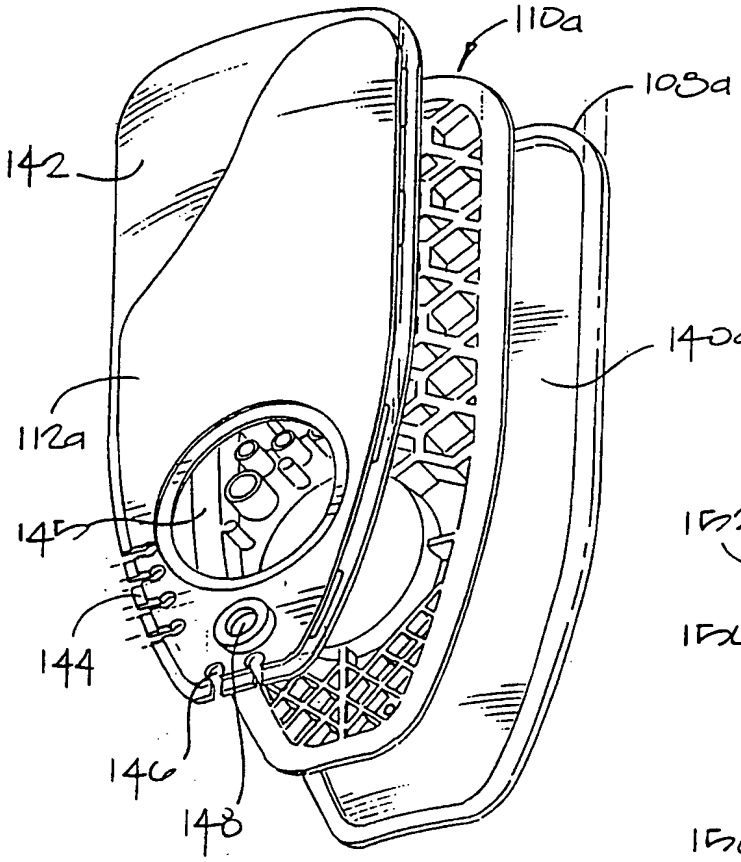


FIG. 2



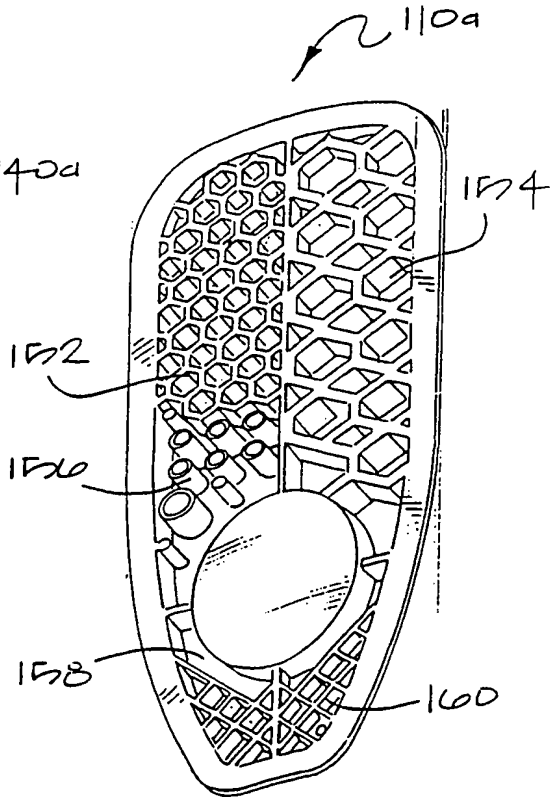


FIG. 3

FIG 5

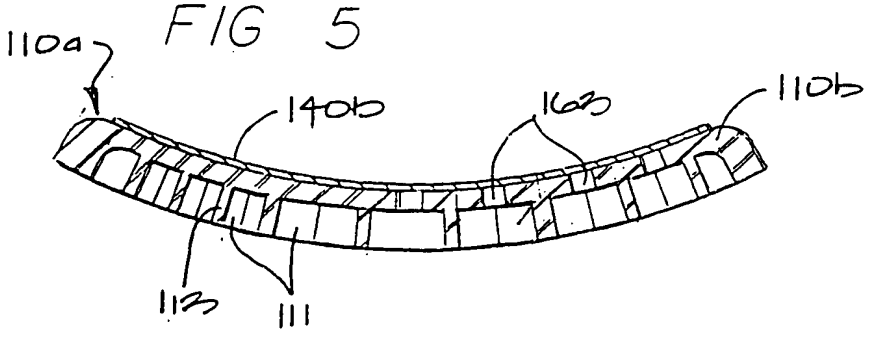


FIG. 4

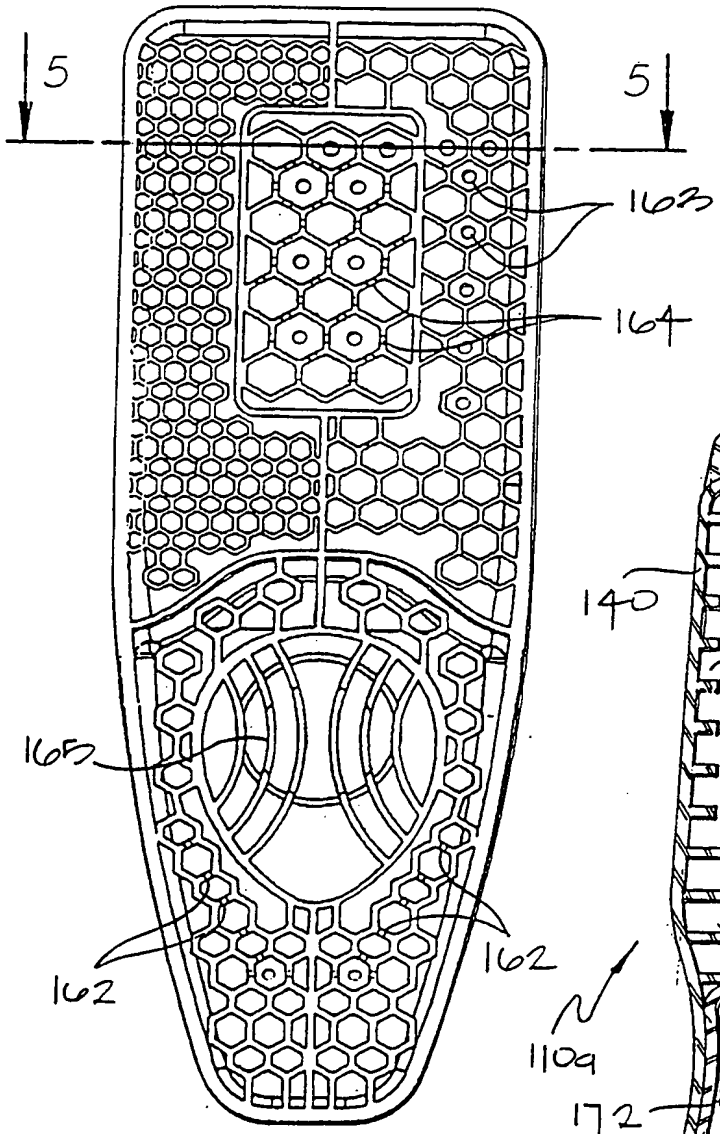
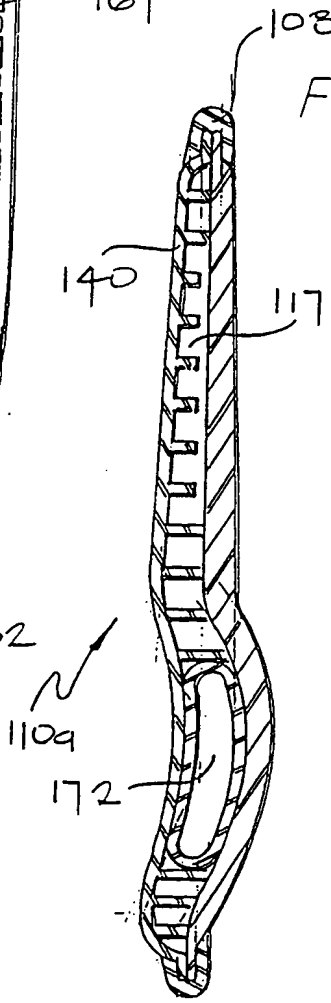


FIG. 6



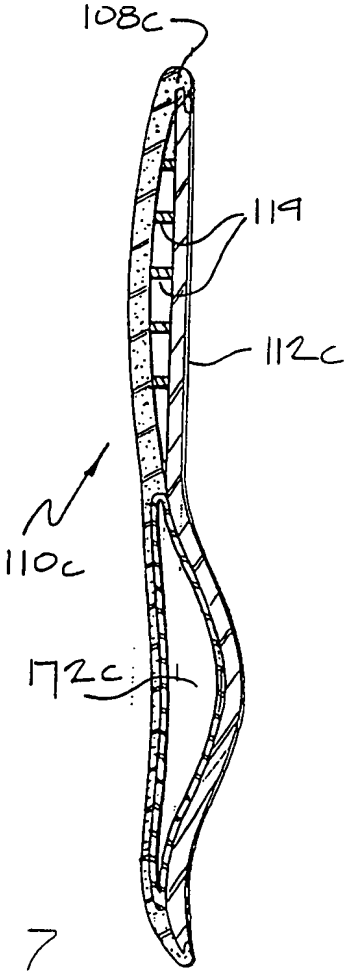


FIG. 7

FIG. 8

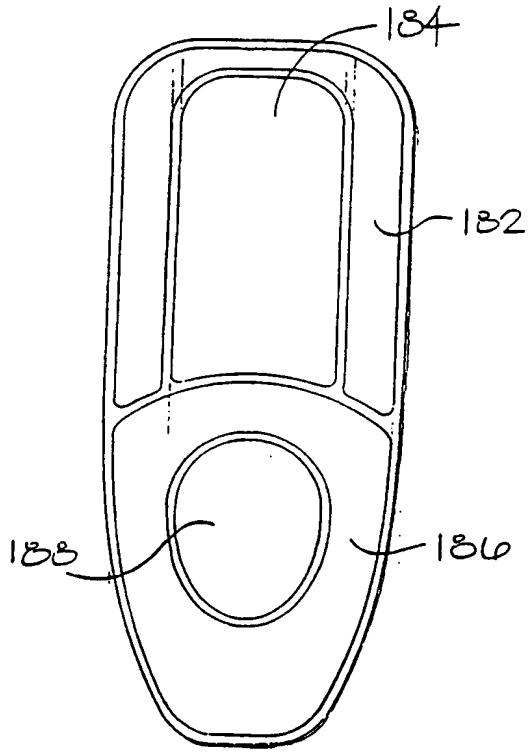


FIG. 10

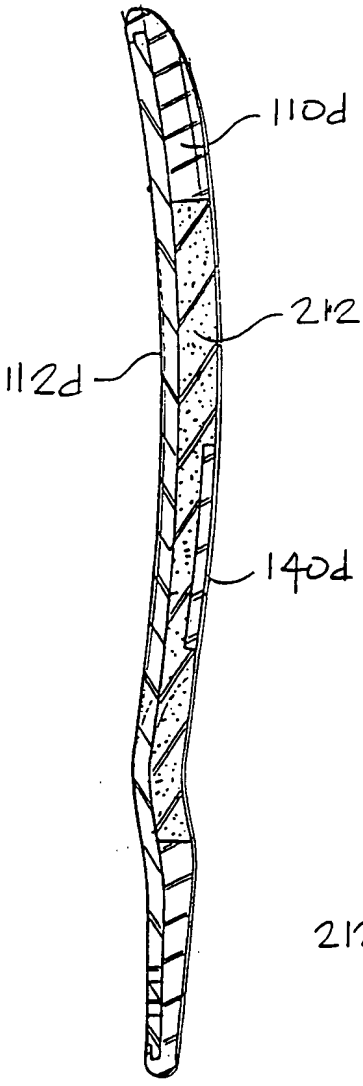
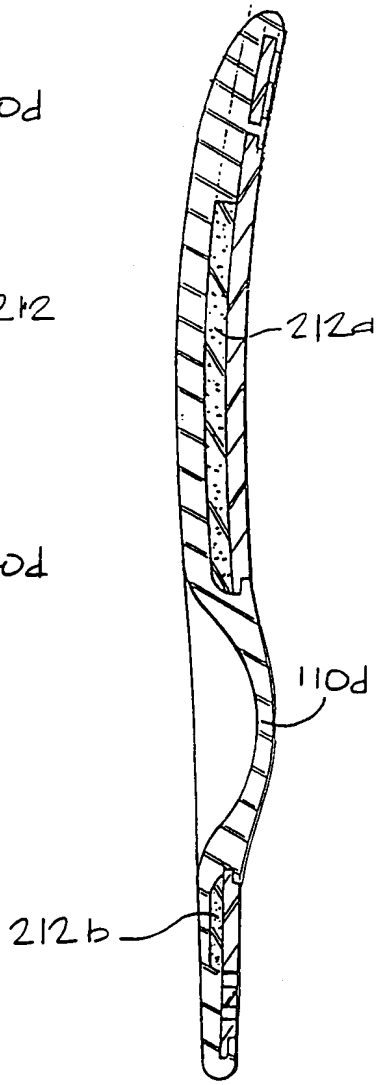


FIG. 11



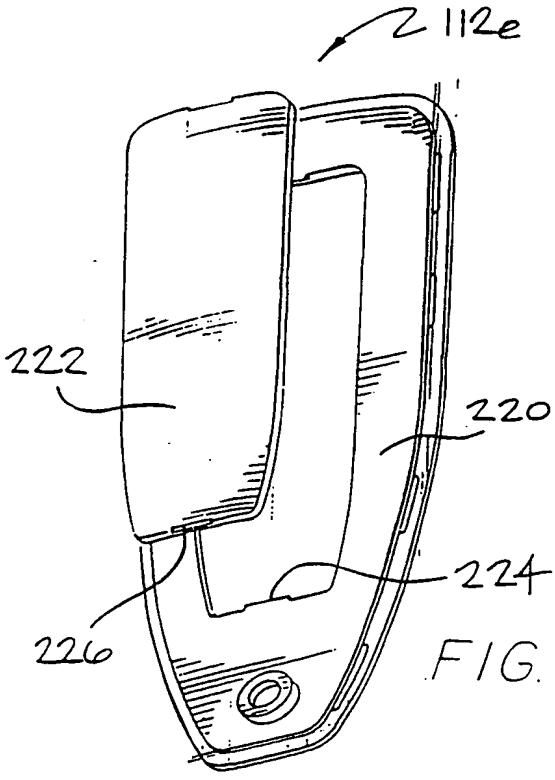
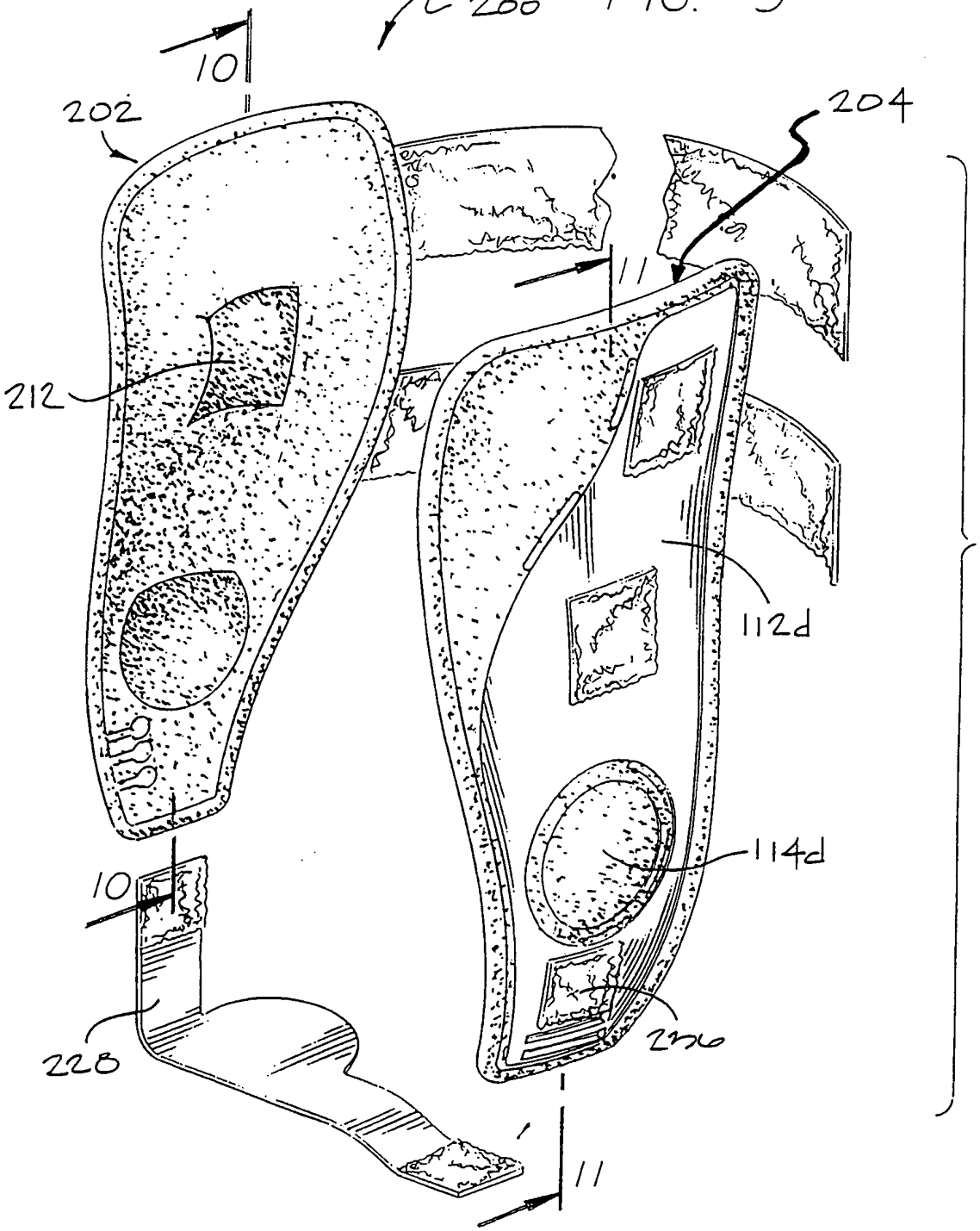


FIG. 12

FIG. 9



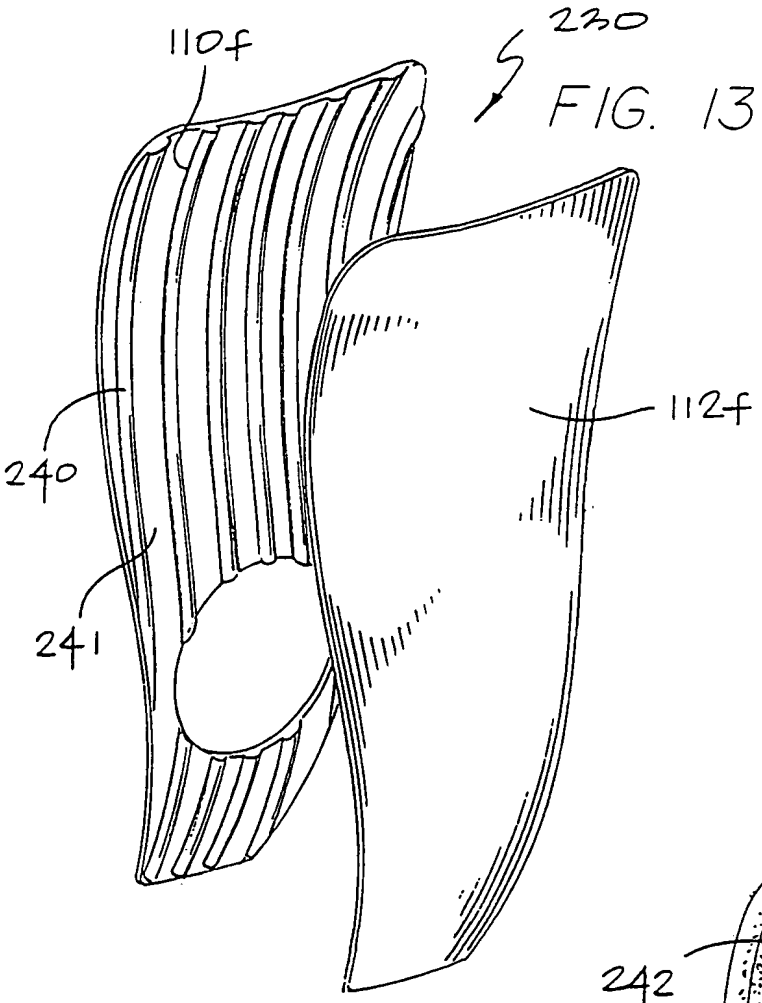


FIG. 13

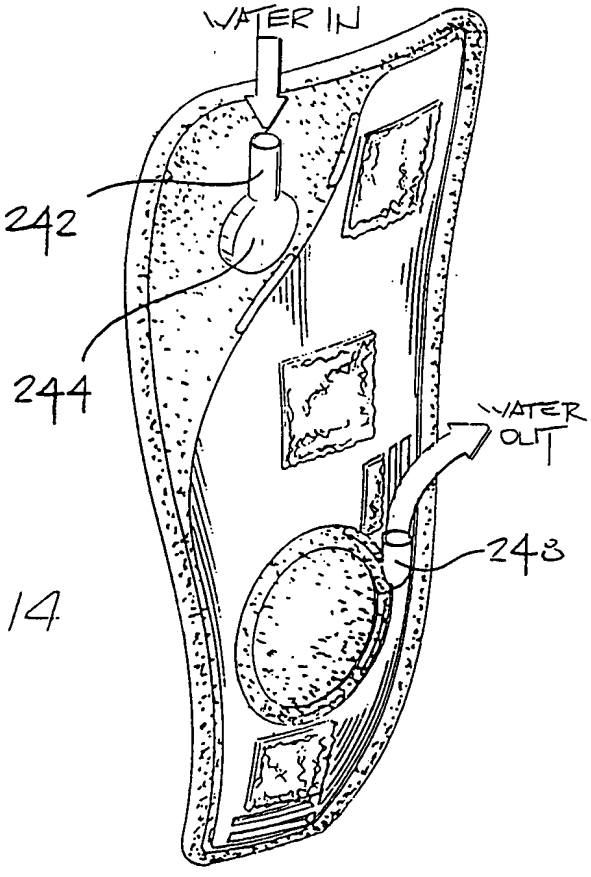


FIG. 14

FIG. 15

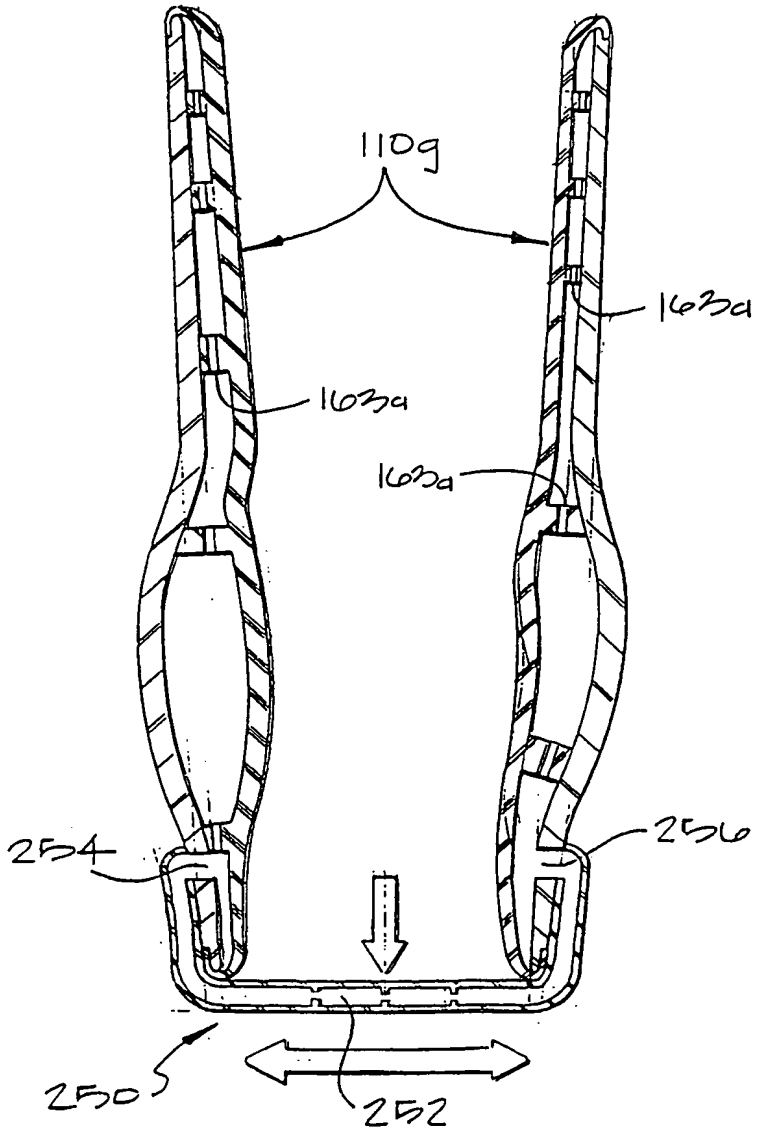


FIG. 16

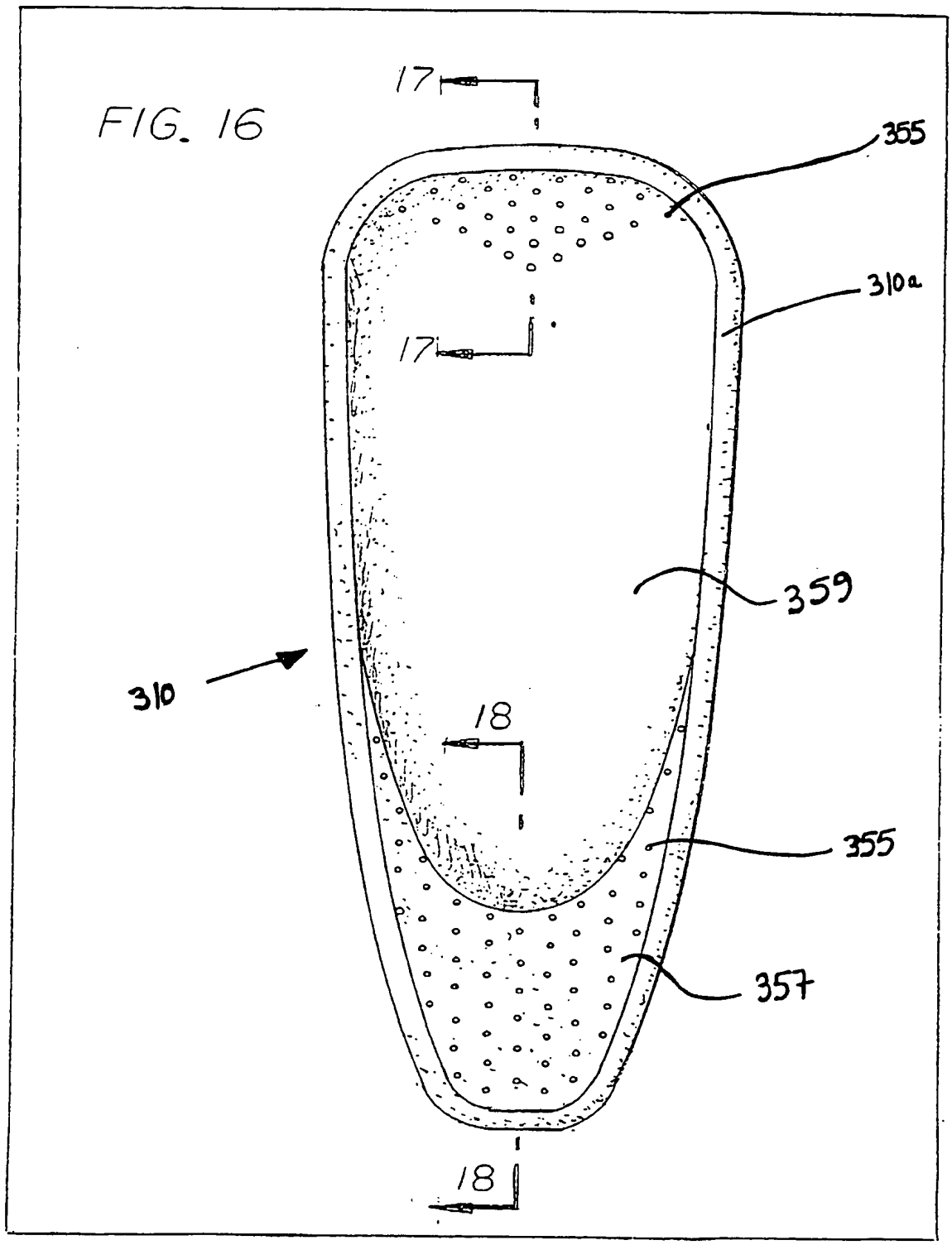


FIG. 17

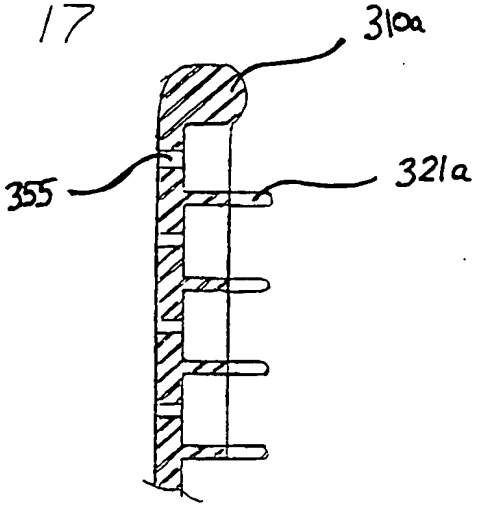


FIG. 18

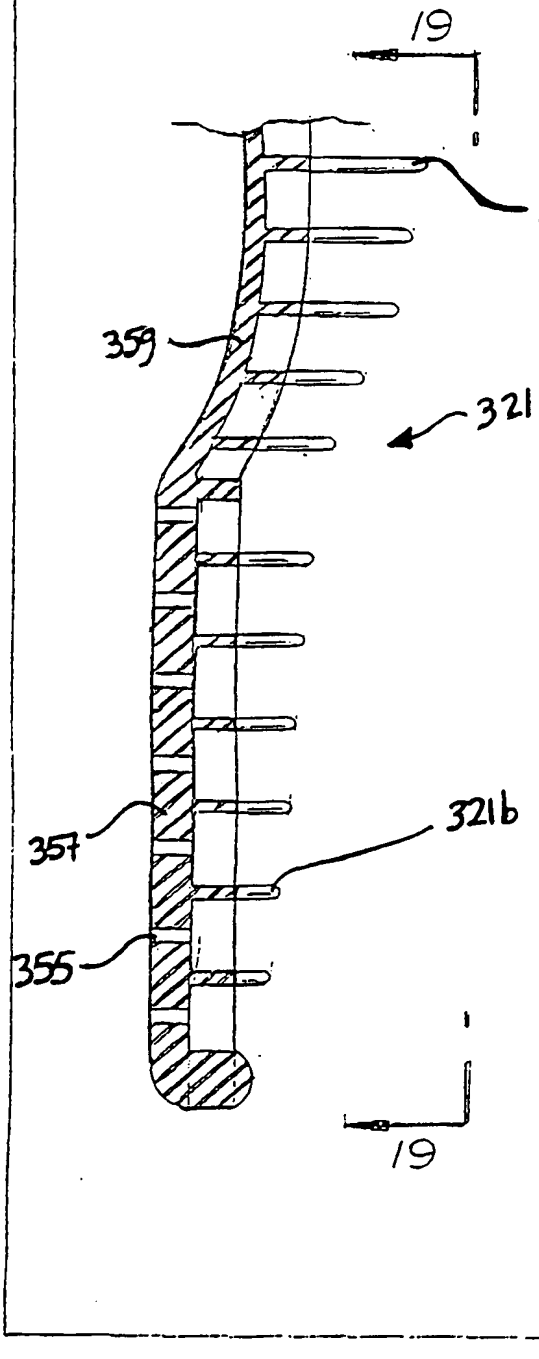


FIG. 19

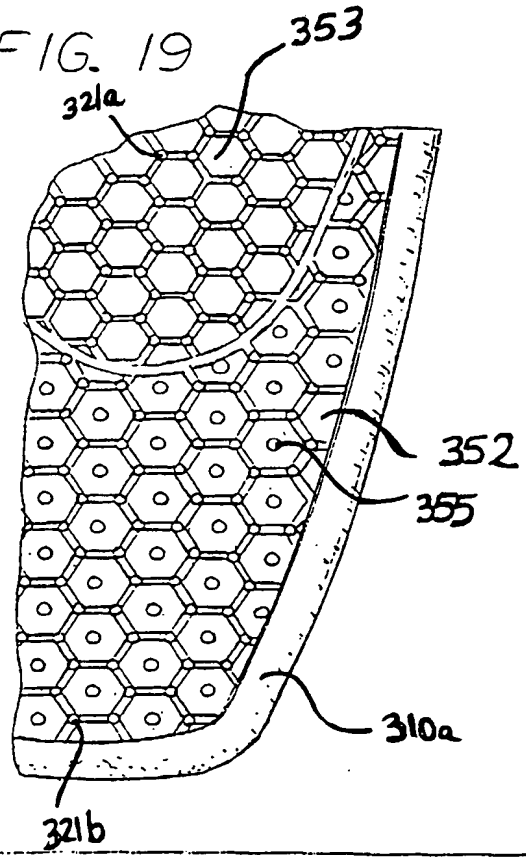
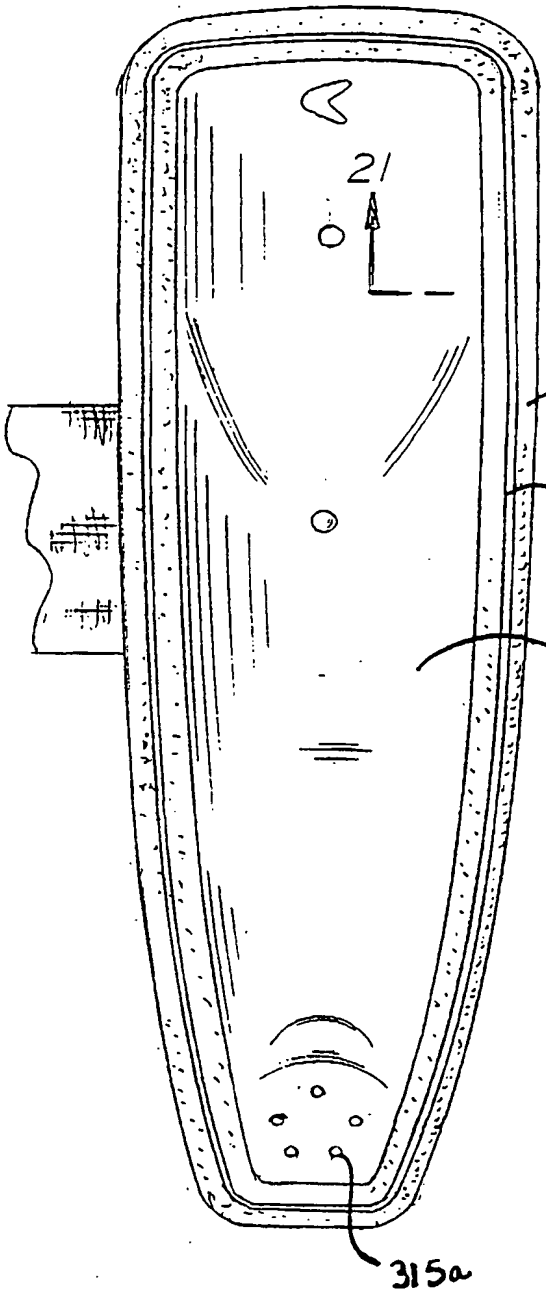


FIG. 20



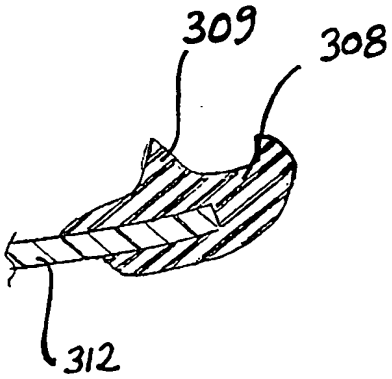


FIG. 21

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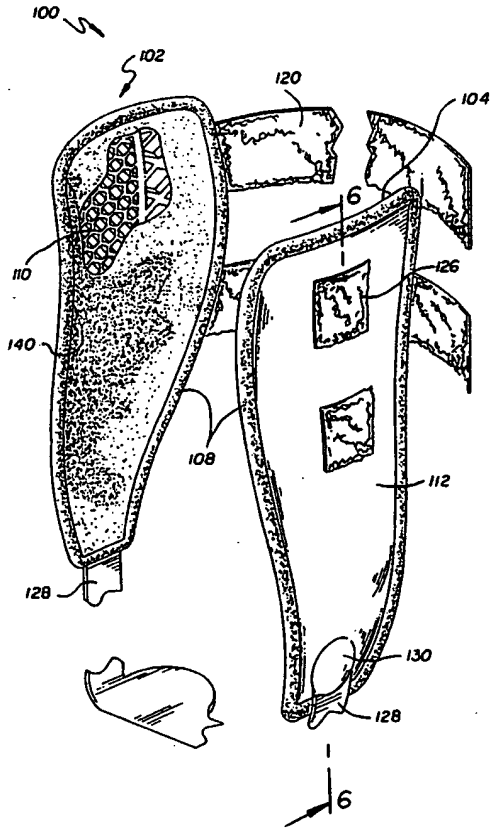
(54) Title: COMFORTABLE ORTHOPAEDIC SUPPORT AND THE METHOD OF MAKING THE SAME

(57) Abstract

An ankle support (100) is constructed using a molded pad (110) and a rigid shell (112). The pad (110) and the shell (112) may be sealed together to form a bladder-pad cushion for comfort. The internal structure of the pad (110) is molded to include geometrically shaped cells of various size, shape and thickness to provide differing levels of localized comfort to the user of the ankle support (100). The pad may be made from a thermoplastic elastomer (TPE) which is spring-like and resists compression sets. The pad may include integrally-molded fingers extending to the shell. The fingers may have different lengths in one or more regions, in order to increase the cushioning effect in a particular region. The pad/shell combination may form a sealed bladder, and a pneumatic pump may be provided in conjunction with the shell so that the user can inflate the bladder.



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COMFORTABLE ORTHOPAEDIC SUPPORT AND THE METHOD OF MAKING THE SAME

RELATED APPLICATION

[0001] The present application is a continuation-in-part of U.S. Patent Application Serial No. 08/705,218, which was filed on August 29, 1996 and which is incorporated by reference herein.

FIELD OF THE INVENTION

[0002] The present invention generally relates to an improved orthopaedic device, and specifically to a orthopaedic support for body limbs or joints with emphasis on the construction of the support for comfort fit.

DESCRIPTION OF RELATED ART

[0003] A variety of orthopaedic supports have been proposed to provide cushioned support to the limb, and most typically to an ankle and the lower leg after an injury. Typically, these ankle supports offer a rigid or a semi-rigid shell for sturdy support with padding for comfort. The padding material typically comprises foam, bladder, or other cushioning material. For example, in the U.S. Patent 4,628,945, granted Dec. 16, 1986 to Glenn W. Johnson Jr., and entitled "Inflatable Ankle Brace with Porous Compressible Filler," an ankle brace comprising a rigid outer shell with an air-inflatable, bladder type liner is described. In that patent, the support is provided by the outer shells and the comfort is provided by the air-inflatable liner. Another design for an ankle brace is disclosed by the U.S. Patent 5,348,530 granted on September 20, 1994, also granted to Tracy E. Grim, William K. Arnold, and Joseph M. Iglesias and entitled "Pneumatic Ankle Brace with Bladder and Pump Arrangement." The '530 patent discloses an ankle brace design with rigid side supports and pneumatic bladder to serve as the cushioning material between the side supports and the wearer's leg.

[0004] Although these patents and others describe the padding materials used to improve the comfort to the person wearing the orthopaedic support, none of the previous

designs suggest the provision in a single structure of different levels of support in different local regions of the limb being supported by the support.

[0005] U.S. Patent No. 5,366,439 to Peters discloses a pad made from several sheets of material, forming closed cells of pressurized air. The cells are all of uniform size and shape and do not provide specialized local support at distinct points on the ankle. The cells must be closed and filled with pressurized air, because otherwise the pad would not provide any support.

SUMMARY OF THE INVENTION

[0006] As an improvement over the prior designs, the present invention discloses a new design for supporting limbs. In this specification, the inventive design will be exemplified in ankle supports. The ankle support of the present invention provides for a creative way of forming and utilizing injection-molded resilient material, preferably thermoplastic elastomer (TPE) pads, to provide a light weight, durable padding while allowing for varying the degree of localized cushioning for different areas of the ankle support. Utilizing the injection molding technology, the resilient pads may be contoured and shaped to highly detailed designs. In addition to the varying the degree of localized support and cushioning, the orthopaedic support of the present invention may be used to provide the ideal levels of compression to the portions of the limb being supported.

[0007] An orthopaedic support for comfortably supporting a limb is disclosed in the present specification. As a typical application of the orthopaedic support, an ankle support will be discussed in this specification. The ankle support includes a outer shell formed for fitting about the limb, such as the lower leg, and a pad. A molded thermoplastic elastomer (TPE) pad is placed in between the outer shell and leg. The shell and the pad may be secured together by various means including infra-red welding, induction welding, bonding using adhesives, snap fitting, or overmolding. The pad is preferably made of molded TPE material and has molded structure toprovide differing levels of cushioning support for the wearer of the orthopaedic support.

[0008] The rigid shell of the ankle support may be formed to accommodate the malleolus or ankle bone when fitted on the user. Alternatively, the shell may be configured to surround but not cover the area around the malleolus. In that case, only the resilient padding may be configured to cover the malleolus.

[0009] The pad is welded on the shell or attached using other suitable methods. Alternatively, an overmold may be used to attach and may seal the resilient padding to the shell. The overmold may be of same material as the padding. If an overmold is used, the securing is accomplished by molding the overmold material at least around the edges of the ankle support. If the overmold material is the same material as the pad, then the overmold may be a mere extension of the pad and the boundary between the pad and the overmold may not be distinguishable.

[0010] Instead of using an overmold to seal the pad onto the shell, the pad, having at least one smooth, continuous side, may be welded directly onto the shell to seal the assembly.

[0011] A liner may be provided to cover the pad. The liner may be of a material such as cloth or other moisture absorbing material for more comfortable engagement with the skin of the user.

[0012] Typically, the TPE pad comprises a substantially continuous smooth side, and an opposing side with molded protrusions or cells. The TPE pad is then sealed to the shell with the opposing side having the protrusions or cells facing the shell. If the seal is an air-tight seal, the shell-pad seal defines a bladder. Alternatively, the TPE pad itself may be configured as a bladder with cell structures built inside the bladder. This may be accomplished by placing a film of similar material on the open side of the cells and sealed around the outside to create a bladder, using the cells to prevent bottoming out during use. Alternatively, the molded pad provided with cells may be placed between two layers of air/fluid impervious film that are sealed around their periphery. In any case, the protrusions built within the interior of the TPE pad, which may be domes, cylinders, or other regularly or irregularly shaped protrusions, define the interior space of the ankle support and provides

for differing levels of localized cushioning determined by the shape, size, and density of the protrusions, or cells, as well as the thickness of the walls of the cells. If the protrusions are shaped to define geometric areas such as rectangles, cylinders, etc., then each of the protrusions may be called a cell. The cell structure, defining the internal structure of the bladder, will be further discussed in the "Detail Description of the Preferred Embodiment(s)" section below.

[0013] To secure the orthopaedic support to the ankle and the lower leg, straps, buckles, or other suitable devices may be attached to the supports. Also, a heel strap, attached near the bottom of each of the ankle pads, connects the ankle supports to each other. The heel straps are adjustable to fit the size of the wearer of the ankle support.

[0014] In accordance with one broad aspect of the invention, a pair of ankle supports for comfortably supporting the ankle are formed to conform to the shape of the ankle and the lower leg, and includes, for each of the supports, a shell and a resilient, preferably TPE pad for cushion. The pad includes molded geometric shaped cells within the pad to provide differing levels of localized cushioning.

[0015] In accordance with another broad aspect of the present invention, an orthopaedic support bladder pad is formed out of thermoplastic elastomer (TPE). The bladder pad is injection molded to include a space within its interior.

[0016] The space interior to the bladder pad may be filled with trapped air, or foam material, or geometric shaped cell structures made of the TPE material to provide differing levels of localized cushioning. The geometrically shaped cells may be interconnected via molded channels to allow air and/or fluid to pass between the cells.

[0017] The present invention also discloses a new method of manufacturing the comfortable ankle support. In accordance with a broad aspect of the present invention, the comfortable ankle support may be manufactured by forming a rigid shell for fitting about the lower leg, placing a resilient pad against the shell, and welding or otherwise bonding the resilient pad to the shell. The resilient material used for the padding is typically a thermoplastic elastomer (TPE); however, the resilient material may be other than the TPE

such as gels, thermoplastic urethane (TPU), thermoplastic rubber (TPR), two part urethanes, or foams, and the resilient material may be secured to the shell by overmolding with either a rubber or a plastic compound.

[0018] The orthopaedic support may include a heel bladder, connected to the side pads for providing varying pressures applied to the lower leg, as the patient walks.

[0019] In an alternative embodiment, the support may be provided with fingers that extend from the support to the ankle in order to provide cushioning to the ankle. The fingers may be of uniform length, or may have different lengths in different regions of the support. The fingers may be arranged at predetermined locations about the periphery of individual cells. The corresponding cells may be of different shapes in different regions. The length of the fingers and the shapes of the cells may be adjusted to customize the comfort and padding of the support in particular regions.

[0020] In a further alternative embodiment, the overmold may be molded about the edges of the shell rather than about the edges of the pad. The overmold may also be provided with a ridge that extends about the periphery of the overmold on the interior side of the shell, for bonding the pad onto the overmold.

[0021] Other aspects, features, and advantages of the present invention will be apparent to those persons having ordinary skill in the art to which the present invention relates from the foregoing description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] FIG. 1 is a diagrammatic, perspective view of a comfortable orthopaedic support as exemplified by comfortable ankle supports illustrating the present invention;

[0023] FIG. 2 is an exploded view of the ankle support shown in FIG. 1, and illustrating the construction of the ankle support;

[0024] FIG. 3 is a perspective detailed view of the internal cell structure of the thermoplastic elastomer (TPE) pad illustrated by FIG. 2;

[0025] FIG. 4 illustrates various internal geometric shaped cells and channels of the TPE pad;

[0026] FIG. 5 is a partial transverse cross-sectional view of the pad shown in FIG. 4 taken along lines 5-5 of FIG. 4.

[0027] FIG. 6 is a cross-sectional side view illustrating the structure of one alternative embodiment of the ankle support shown in FIG. 1, taken along lines 6-6 of FIG. 1;

[0028] FIG. 7 is an cross-sectional side view of an alternative embodiment of an ankle support;

[0029] FIG. 8 illustrates the areas of the ankle support which may require differing levels of cushioning and support;

[0030] FIG. 9 is a diagrammatic, perspective view of an alternative embodiment of the ankle support of the present invention employing foam material for cushioning;

[0031] FIG. 10 is a cross-sectional side view illustrating the ankle support pad structure, taken along lines 10-10 of FIG. 9;

[0032] FIG. 11 is a cross-sectional side view illustrating the ankle support pad structure of an alternative embodiment;

[0033] FIG. 12 illustrates an alternative embodiment of the shell with a removable core for varying the rigidity of the shell;

[0034] FIG. 13 illustrates an alternative embodiment of the ankle support and pad in which a channeled pad is employed;

[0035] FIG. 14 illustrates inlet and outlet ports and valves of an ankle support useful for hot and/or cold therapy; and

[0036] FIG. 15 is a cross-sectional view of another embodiment of the present invention;

[0037] FIG. 16 is a rear elevational view of the exterior of an alternative embodiment of a pad according to the present invention;

[0038] FIG. 17 is a cross-sectional view taken across line 17-17 of Fig. 16;

[0039] FIG. 18 is a cross-sectional view taken across line 18-18 of Fig. 16;

[0040] FIG. 19 is a detail perspective view of an interior portion of the pad of Fig. 16;

[0041] FIG. 20 is a perspective view of a shell to which the pad of Fig. 16 is to be bonded; and

[0042] FIG. 21 is a cross-sectional view taken along line 21-21 of Fig. 20 illustrating the overmold that is molded about the edges of the shell itself.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

[0043] Referring to the drawings, particularly to FIG. 1, a comfortable orthopaedic support 100 is shown. As a preferred embodiment of the present invention, and to facilitate the description of the present invention, this section of the document will discuss comfortable ankle supports. However, comfortable orthopaedic supports in accordance with the present invention may be manufactured for and applied to other parts of the body.

[0044] FIG. 1 illustrates an ankle brace including an ankle support 102 for the medial side of the lower leg and a cooperative ankle support 104 for the lateral side of the lower leg. However, because the ankle support design of the present invention is applicable for either one or both sides of the lower leg, the following discussions will not differentiate between the medial and the lateral side supports. The ankle support comprises a rigid outer support, or a shell, 112, and a thermoplastic elastomer (TPE) pad 110. The shell 112 and the pad 110 may be welded together or may be sealed together by an overmold 108 at least around the edges. The overmold 108 may be an extension of the TPE pad 110 and made of the same TPE material as the pad 110. A flexible layer 140 is preferably integral with pad 110, but may be separate and bonded thereto. The rigid side support 112 may be shaped to accommodate the ankle or the malleolus area. The TPE pad 110 has an inner

structure as shown by the cut-away area to various geometric shapes to provide differing levels of localized comfort. The interior design of the pad 110 will be further illustrated by the following figures and the corresponding discussions below. A heel strap 128 is attached to the lower portions of both of the ankle supports by a cap 130.

[0045] The comfortable ankle support may be secured onto the lower leg using fastening fabric, such as the hook and loop type fastening material sold under the trade name VELCRO®, straps and buckles, or any other suitable means. FIG. 1 illustrates the use of the loop-type VELCRO® straps 120 along with the hook-type VELCRO® sections 126 attached to the shell 112 as the means of securing the ankle supports to the lower leg.

[0046] Although the preferred embodiment of the present invention as disclosed as being implemented using a pair of rigid side supports, the pad 110 may be used as the cushioning member for a unitary ankle support such as the "Adjustable Tension Ankle Support" disclosed by U.S. Patent No. 4,869,267 issued to Tracy E. Grim and Thomas M. Smario.

[0047] FIG. 2 is an exploded view of an ankle support illustrating the construction of the ankle support and its internal structure. Incidentally, Fig. 2 is shown flat for convenience and clarity in showing the internal construction, but would actually be curved and contoured to the general shape of the ankle as shown in Fig. 1. Figs. 3, 4, 8 and 12 have also been illustrated as being flat, but would actually be curved in configuration. Returning to Fig. 2, the shell 112a as illustrated may be partially covered by the TPE material 142 which may be an extension of the overmold 108a which may also cover the TPE pad 110a. The pad 110a is placed in between the outer support, or rigid shell, 112a and the inner liner 140a. The liner 140a may be of same TPE material as the pad 110a or other suitable materials such as cloth, neoprene, etc. Alternatively, the liner 140a may not be necessary if the pad 110a has a substantially continuous skin on the side of the pad upon which the liner is expected to attach to. The overmold 108a may comprise the resilient material which seals the shell 112a to the pad 110a. The inner cell structure of the TPE pad will be illustrated in detail by FIGS. 3 and 4 and described by the corresponding discussions below. If the pad

110a is welded to the shell 112a, the overmold 108a may not be a necessary element of the ankle support.

[0048] The rigid outer support, or the shell, 112a may be formed of relatively stiff or semi-rigid plastic, and may include cutouts 144 and 146 which serve to increase the shell's flexibility near the malleolus area 145 to increase the comfort and to decrease the chance of the shell 112a digging into the often sensitive ankle region. The cutouts 144, 146 may be implemented on any portion of the shell 112a to increase the flexibility of the shell 112a for the area. A receptacle 148 is provided near the bottom of the shell 112a to allow the attachment of the heel strap 128 of FIG. 1 by welding, snap-fit with a retention cap, rivet, or other suitable attaching means.

[0049] The liner 140a of the ankle support is substantially smooth. The overmold 108a as utilized substantially covers at least the outer edges of the TPE pad 110a, the liner 140a, and the shell 112a forming an air-tight seal and trapping air.

[0050] Again, if the pad 110a is welded or bonded onto the shell 112a and if the pad 110a includes a substantially continuous surface (for the side away from the shell), then the liner 140a and the overmold 108a are not necessary elements of the ankle support.

[0051] In the embodiment as shown by FIG. 2, the shell 112a surrounds but does not cover the malleolus or protruding portion of the ankle, allowing the malleolus to extend into the ankle support. That area is covered only by the outer surface of the TPE pad 110a or the liner 140a.

[0052] In an alternative embodiment, the shell itself includes the overmold about its edges. A pad is molded separately, and the edge of the pad is bonded to the overmold The liner 140a would either be molded with the lip, or would be a separate material onto which the lip 108a is molded.

[0053] FIG. 3 provides a detailed perspective view of the interior design of the TPE pad 110a. The TPE pad 110a is injection molded to include various protrusions or cells. These cells may be molded as domes, pyramidal or other regularly or irregularly shaped

geometrical protrusions. The embodiment as illustrated by FIG. 3 includes various sized hexagonal cells resembling honeycomb structures 152 and 154, cylindrical cells 156, criss-cross or checkered-patterned cells 160, and irregularly shaped cells 158. The size, shape, and density of the cells as well as the thickness of the walls defining the cells determine the level of cushioning for the local areas of the ankle support.

[0054] The utilization of the injection molded TPE material for orthopaedic supports has many advantages. First, the TPE pad can be molded to include detailed designs such as geometrically shaped cells. The TPE pad can be specifically contoured to the malleolus areas, the calf, and the calcaneal regions of the support. Although the TPE material is more dense than other padding materials such as foam, the innovative design including molded cell-structure as illustrated by FIGS. 2-7 overcomes this disadvantage by reducing the weight of the product. The reduction in the weight of the pad also translates into lower cost and increased value to the end user of the product.

[0055] One suitable thermoplastic elastomer (TPE), is available under the name RIMFLEX, made from KRATON® Polymer. It is produced by Shell Oil Company and is available from Synthetic Rubber Technologies of Uniontown, Ohio. There re many other sources of thermoplastic elastomers. The material may be molded by any of the numerous injection-molding companies across the nation. Other material may be used in place of the TPE, including thermosetting and thermoplastic materials.

[0056] Continuing to refer to FIG. 3 but also referring to FIG. 4, the geometrically shaped cells of the pad 110 may be interconnected via channels 162 and 164 as illustrated by FIG. 4. The figure illustrates channels 162, molded between the cells of the TPE pad 110a to allow passage of air or fluids amount the cells of the pad 110a. The channels provide the means for the movement of the air or fluids between the cells, creating a massaging effect on the lower leg, thereby promoting blood flow. Also, the channels may be designed in a manner in which external fluid may be circulated with the ankle pad for hot and cold therapies.

[0057] FIG. 4 also illustrates the fact that the cells of the pad 110a may be molded to include shapes such as logos and trademarks as well as geometrical shapes as indicated by reference number 165.

[0058] FIG. 5 is a partial transverse cross-sectional view of the TPE pad embodiment as shown in FIG. 4 taken along the line 5-5. The geometric cells 111 are defined by its walls 113. In the embodiment as shown, the pad 110a includes a smooth, substantially continuous side 110b eliminating the need for a liner 140 of FIG. 2 for this embodiment. However, even though not required, a liner 140b still may be used to increase comfort.

[0059] FIGS. 4 and 5 also illustrate that the cells of the pad 110a may include openings 163 on its smooth side allowing air to pass in and out of the pad to relieve pressure. If the liner 140b is made of cloth or other breathable material, the openings 163 do not have to extend through the liner 140b.

[0060] Referring now to FIGS. 6 and 7, cross-sectional side views illustrating the internal structure of the ankle supports of FIG. 1 are illustrated. Referring specifically to FIG. 6, a cross-sectional side view of the ankle support is illustrated. The shell 112 provides rigid or semi-rigid support for the ankle support and the TPE pad 110 provides the cushioning for the ankle support. The TPE pad 110 includes geometrically shaped cell structures. The overmold 108 may seal the TPE pad 110 and the liner 140 to the shell 112. If the seal is an air-tight seal, and the liner 140 (which is an integral part of the pad 110) includes no openings as illustrated by the reference number 163 of FIG. 4, then a bladder is formed. In the embodiment as shown, the shell 112 covers the entire lower leg including the malleolar area. Also, the TPE pad 110 may include a smaller, internal bladder 172 around the malleolus area providing additional level of cushioning.

[0061] Alternatively, instead of a bladder 172, the additional cushioning may be provided by inserting other soft material in the space such as open cell foam material or gels.

[0062] Reference number 117 shows that the structures for the pad 110 may be formed such that the TPE material does not span the entire distance from the liner 140 to the shell

112 creating a pressure free travel of the padding 110 to the shell 112. The pressure free travel design provides for unsurpassed softness and comfort for the area of the pad. This technique allows additional air to be trapped under the pad 110 and creates additional room for the pad 110 to flex for softer cushioning. Also, the reduction in the amount of material used for the pad 110 leads to a lighter ankle support and reduced production costs.

[0063] An alternative embodiment of the ankle support is illustrated by FIG. 7. Similar to the ankle support as shown by FIG. 6, the shell 112c and the TPE pad 110c are sealed to each other by an overmold 108c substantially molding at least the edges of the shell 112c and the pad 110c. However, unlike the embodiment of FIG. 6, the pad 110c of FIG. 7 does not include internal geometric structures for cushioning. The pad 110c includes only an internal bladder 172c around the malleolus area.

[0064] In the embodiment of the present invention as illustrated by FIG. 7, the cushioning is provided by internal structures molded directly onto the shell 112c as illustrated by reference number 119. In this embodiment, the cell structures for the padding, such as the geometric configurations shown in other figures, has been initially molded directly on the shell 112c. Subsequently, the layer 108c is bonded to the shell 112c around the edges of the shell, leaving the open spaces defined by the molded cell structures 119.

[0065] Utilizing the geometrically shaped cells molded onto the TPE pad, the ankle supports 102, 104 of FIG. 1 may provide differing levels of cushioning to the different areas of the lower leg being protected by the ankle support. FIG. 8 illustrates one possible map of the areas of the ankle support which may require different levels of cushioning. For instance, the malleolus area 188 may require very soft support using a configuration indicated by reference number 117 of FIG. 6 or could be provided by an internal bladder-type structure 172c as shown in FIG. 7. Using the construction shown at 117 in Fig. 6 would allow some distance for free travel, with increasing resistance, and protection against bottoming out. The area 186 surrounding the malleolus may require a soft cushioning, slightly firmer than the area 188, to avoid aggravation of an injured malleolus. The area

184 supporting the lower tibia may require firm support and its surrounding area 182 may require softer cushioning for comfort. The softer cushioning around the edges of the support prevents the edges of the shell from digging into the wearer's leg. As already indicated, the degree of cushioning of these areas may be predetermined. Other mapping schemes may be used to support the ankle region or to support other limbs of the body.

[0066] An alternative embodiment of the orthopaedic support 200 is illustrated by FIG. 9. The ankle supports 202 and 204 of this embodiment of the orthopaedic support 200 include other cushioning materials in addition to TPE pads as described above. The additional cushioning may be provided by the embedded cushioning material 212. Typically, the material used for the embedded cushioning is foam or gels. Because the TPE material is more durable (tear-resistant), flexible, water resistant, and hypo-allergenic than foam material, it makes a better padding for ankle supports. However, because of its higher density, it may not provide cushioning which is as soft as may be desired, and could involve some increase in weight. Using the design illustrated by FIG. 9, the benefits of the TPE pad may be retained while gaining the additional cushioning and reduction in weight, provided by the foam core 212.

[0067] In short, FIGS. 1-8 illustrate an embodiment of the ankle support of the present invention where the padding for the support is created using injection molded TPE pads with internal geometrically shaped cells. Alternatively, FIGS. 9-11 illustrate an embodiment of the ankle support of the present invention where the padding for the support is created using a molded TPE pad with a cushioning core of a different material.

[0068] Also illustrated by FIG. 9 is the adjustable heel strap 228 which may be detachably mounted to the ankle supports using the loop and hook type mounting member 236 which, in turn can be affixed to the lower portion of the ankle supports permanently or by a snap-on unit or other suitable attaching means.

[0069] The shell 112d of the ankle support 202, 204 may be formed to surround but not cover the malleolus area 114d, with the trampoline cushioning effect resulting from the lack of rigid coverage in the malleolus area allowing less padding in that area.

[0070] Referring to FIGS. 10 and 11, cross-sectional side views illustrating the ankle support pad structure, taken along lines 10-10 of FIG. 9 is shown. The foam pad 212 is embedded in the TPE pad 110d between the shell 112d and the outer surface 140d of the TPE pad 110d. This construction increases the cushioning of the TPE pad 110d while maintaining the water resistance, durability, and other favorable characteristics of the TPE pad.

[0071] Alternatively, for the cross section of the ankle support as illustrated by FIG. 11, the embedded foam pad 212a, 212b does not cover the malleolus area. Rather, the foam pad surrounds the malleolus area as indicated by 212a and 212b. As illustrated by FIG. 11, only a layer of the TPE pad 110d covers the malleolus area. This creates a "trampoline" type effect. The malleolus, as illustrated by the figure, is covered by a TPE "trampoline," which provides a flexible padding without the rigid shell. The foam pad 212a and 212b of may be replaced by gel because, unlike the design illustrated by FIG. 10, the space defined 212a and 212b is completely enclosed by the TPE over pad 110d.

[0072] FIG. 12 illustrates an adjustable shell design applicable to the present type of ankle support. The shell 112e may comprise a rigid or semi-rigid plastic shell frame 220 and a shell core 222 which may be removable. The removable shell core 222 may be replaced with more or less rigid shell cores as the needs of the patient change over time. The initial shell core 222 may be of a very rigid material so that prevention of inversion or eversion is greatest, thereby allowing the patient to regain stability in his or her ankle. Once the ankle has healed and the patient is ready for more demanding forms of exercise, the shell core 222 may be changed to a less rigid material so as to allow further movements of the ankle. Further, the shell core 222 may be removed entirely for further flexion, if desired. In the embodiment as illustrated by FIG. 12, the shell core 222 fits snugly into the shell frame 220, and snaps into place. The snapping action is accomplished using a protrusion 224 and the indentation 226.

[0073] The arrangement of Fig. 12 can also be employed as a "trainer" style ankle support to prevent injury to an ankle that has healed somewhat but which requires protection from reinjury. In the "trainer" embodiment, the outer shell 220 is made from a

flexible material such as a low density polyethylene or polypropylene. An insert 222 may be made from a material that is more rigid than the flexible outer shell 220, such as high density polyethylene, steel, nylon and other rigid materials.

[0074] In the preferred embodiment that Fig. 12 illustrates, the insert 222 snaps into place on the shell 220. However, the insert may alternatively be secured to the shell 220 in other ways, such by riveting, with adhesive, or by welding into place. An advantage of this arrangement is that the insert 222 may be secured into place immediately after the ankle is injured. However, after the ankle has healed somewhat, the insert 222 may be removed from the outer shell 220, making the support more flexible and allowing the person wearing the support to engage in a wider variety of activities.

[0075] Yet another alternative embodiment of the ankle support is illustrated by FIGS. 13 and 14. Referring to FIG. 13, the ankle support 230 is illustrated with a shell 112f and the TPE pad 110f with molded tubular channels 240 and grooves 241 as its inner surface. Such design is particularly useful for hot and cold treatments of the ankle and the lower leg. FIG. 14 illustrates a water intake port 242 and an intake valve 244 and a water outlet port and an outlet valve 248.

[0076] Another alternative embodiment of the orthopaedic support of the present invention is illustrated by FIG. 15. The heel member 250 comprises a bladder 252 linked via channels 254, 256 to the ankle supports which has its TPE pads 110g configured as bladders as well. Each time the foot of the wearer presses down on the heel member 250, the air or the fluid within the bladder 252 is pressured into the bladder-pad 110g of the ankle supports thereby massaging the lower leg. The pads or bladders 110g may be as shown in earlier figures of the drawing, and may have channels 163a interconnecting the cells of the pads. The channels 254, 256 may be formed integrally with the heel bladder 252, or separate air channels or tubes may be provided to interconnect the heel bladder 252 with the side pads 110g.

[0077] Figs. 16-20 illustrate a further alternative embodiment of the present invention. In this embodiment, the support is provided with a plurality of thin "fingers" 321, which are

most clearly seen in Figs. 17 and 18. The fingers 321 are molded about the periphery of the respective honeycomb cells 352 and 353. The fingers extend from the molded interior elastomer pad 310 of the support to the hard outer plastic shell 312 (Fig. 20). The entire interior elastomer pad 310, which has an edge 310a, can be molded in a single injection molding step to simplify manufacturing.

[0078] The aspect ratio of the fingers 321 are varied to provide more or less cushioning in particular regions of the support. For example, Figure 18 illustrates the change in finger heights in different regions of the pad, including longer fingers 321a and shorter fingers 321b. In much of the support, the fingers 321b are relatively short with respect to the diameter of the fingers. On the other hand, the fingers 321a are considerably longer than the fingers 321b in the rest of the pad. Consequently, the area or areas of the support having the longer fingers 321a will provide more cushioning than the areas of the support having the shorter fingers 321b. That is, the longer fingers 321a flex more than the shorter fingers 321b in response to pressure on the support from the ankle.

[0079] The fingers 321a,b also serve to space the flexible inner portion of the support from the hard outer portion of the support. Consequently, the longer fingers 321a provide additional space between the malleous of the ankle and the hard outer shell 312 of the brace. The malleolar region of the ankle is typically where the ankle is injured, and the injury may be exacerbated if the injured portion of the ankle hits the hard outer shell of the support. The longer fingers prevent the malleous from hitting the hard outer shell during use, and provide softer cushioning which makes the brace more comfortable for the wearer during healing.

[0080] It should be noted that the outer shell 312 in Fig. 20 includes air holes 315a that allow air within the support to ventilate in and out. In this embodiment of the invention, the cells support the ankle without the need for pressurized air. That is, the structure of the cells themselves rather than pressurized air provide the support for the ankle. This is in contrast to pressurized-air types of supports, which do not provide cushioning unless the support is inflated prior to use.

[0081] Additional air holes 355 may be included in the pad 310 itself. For example, the pad 310 in Fig. 16 has numerous air holes in both the bottom and top portions of the pad. Consequently, air is free to flow in and out of the spaces between the pad and the shell. This may be advantageous in, for example, high altitude locations where the air pressure in an air-filled bladder relative to the ambient pressure may become greater than desirable. The present embodiment of the pad, which does not inflate with air, therefore does not have a problem with air pressure in high altitudes.

[0082] As an additional alternative, the thickness of the pad walls may vary in different regions of the pad. For example, the wall thickness of the pad of Fig. 18 is greater in the lower region of the pad 357 than in rest of the pad 359. This is because the lower region of the pad generally corresponds to the area of the ankle that is injured and where there is swelling. Increasing the thickness of the skin causes the pad to feel firmer, and decreasing the thickness makes the pad feel softer.

[0083] A pad having varying skin thickness is preferably formed by injection molding. However, other methods in which a liquid material solidifies to form to the shape of the mold, such as (for example) reaction-injection molding or pour molding may be employed. To vary the thickness of the skin of the pad while at the same time forming a pad cell structure and integral fingers generally requires a manufacturing method in which a liquid material fills a cavity defining the desired pad configuration, then solidifying to conform the shape of the pad to the shape of the cavity.

[0084] Referring in particular to Figs. 20 and 21, the shell 312 is provided with an overmold 308 that extends about the periphery of the shell. The overmold is typically formed of the same material as the pad 310, so that the pad can be easily bonded to the overmold. The overmold 308 has a ridge 309 about which the outer edge 310a of the pad extends when the pad is bonded to the overmold. The fingers 321 extend from the pad 310 to the shell 312, with the outer surface of the pad 310 being substantially continuous.

[0085] In the presently preferred embodiment, the pad 310 bonds only to the overmold 308 to secure the pad to the shell. The pad is typically bonded to the overmold with a

conventional solvent that melts material on both the edge 310a of the pad and on the overmold. The melted material then solidifies to form the bond. However, the pad may be bonded to the overmold in other ways, such as by welding or with adhesives. In alternative embodiments, the pad may be adhered directly to the shell.

[0086] In the preferred embodiment of the present invention as illustrated by FIGS. 1-15, a comfortable orthopaedic support is implemented with ankle supports and a heel strap. The ankle supports comprise a rigid shell and padding made from molded thermoplastic elastomer (TPE) with or without other padding material. The TPE pad may be sealed to the shell with trapped air or fluid between the pad and the shell to form a bladder. A lining material may cover the pad. To provide localized comfort, the TPE pad may be molded to include various protrusions or cells toward the shell. These cells may be shaped as domes or other geometric shapes such as honeycomb shapes. Alternatively, soft foam may be embedded between the rigid shell and the durable TPE padding to provide durable surface with soft padding. Another option is to use gel in place of the soft foam or the molded TPE pad. Typically, the overmold which seals the TPE pad to the shell is made of same TPE material as the padding and also partially covers the shell.

[0087] Although the present invention has been described in detail with regarding the exemplary embodiments and drawings thereof and with regarding alternate embodiments, it should be apparent to those skilled in the art that various adaptations and modifications of the present invention may be accomplished without departing from the spirit and the scope of the invention. Thus, by way of example and not of limitation, the present invention has been described as an ankle support. However, it is apparent that the inventive support may be applied to arms, legs, and other part of the body requiring varying degrees of localized comfort. Incidentally, where reference is made hereto to air cells or geometric cells, reference is to macro-cells with dimensions greater than 1/64 or 1/32 of an inch for example, and not to foams. Accordingly, the invention is not limited to the precise embodiment shown in the drawings and described in detail hereinabove.

[0088] Pads according to some of the embodiments of the present invention may be sealed, such that a space is formed between the pad and the shell that can be filled with air

or other fluid to form a fluid bladder. The shell may include an air pump with which the user can inflate the bladder. A release valve can be provided permitting the user to release air from the bladder as necessary.

[0089] It should be noted that the cell structure described in connection with the present invention has additional applications. For example, open cells can be inserted in between two layers of material which together form a bladder. The cells act as reinforcement to the bladder, such that if the bladder deflates or if an especially great load is applied to the bladder, the cell structure reduce the likelihood that the bladder will bottom out.

[0090] While a pad made with a TPE material has been described, and while the inventors presently prefer to make the pad from TPE material, it should be understood that the pad may be made from a variety of other materials. For example (but without limitation) the pad may be made of thermoplastic urethanes, thermoplastic rubbers, silicones, two-part urethane mixtures and poured foams.

[0091] It should be noted that the fingers 321 are shown in the figures as having a generally circular cross-section. However, the fingers can have various other cross-sections, so long as they perform a cushioning function.

[0092] While the pads described herein are particularly well suited for use in orthopaedic supports, there are numerous other applications in which such pads could be employed. For example, embodiments of this type of pad may be employed in various protective devices, such as knee pads, shin guards, and football pads, among other applications where durability and water resistance are desired.

[0093] From the foregoing detailed description, it will be evident that there are a number of changes, adaptations, and modifications of the present invention which come within the province of those skilled in the art. However, it is intended that all such variations not departing from the spirit of the invention be considered as within the scope thereof as limited solely by the claims appended hereto. It is therefore intended that the following claims may be interpreted as covering all such applications, alterations and modifications as fall within the true spirit and scope of the invention.

WE CLAIM:

1. An orthopaedic support for comfortably supporting the ankle of a wearer, comprising:

an outer shell formed for fitting about the lower leg of the wearer;

a molded pad bonded to said shell;

said pad having a surface; and

said pad having a plurality of molded substantially hollow structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, at least some of said structures having a different dimension than others of said structures;

wherein said molded structures comprise walls, said walls providing cushioning support for the ankle even without inflating or otherwise filling said molded structures with air, liquid, gel and the like.

2. An orthopaedic support in accordance with 1 wherein an overmold substantially surrounds said pad and said shell substantially sealing together said orthopaedic support.

3. An orthopedic support as defined in claim 1 further comprising an overmold molded onto said shell, said pad being bonded to said overmold.

4. An orthopaedic support as defined in claim 1 further comprising means for securing said ankle support around the lower leg; and a heel strap for securing said orthopaedic support.

5. An orthopaedic support as defined in claim 1 wherein said pad bonded to said shell forms a fluid-filled bladder.

6. An orthopaedic support as defined in claim 1 wherein an inner liner of cloth is secured to said pad on the surface of said pad facing the lower leg of the user.

7. An orthopaedic support as defined in claim 6 wherein said liner is integrated with said pad.

8. An orthopaedic support in accordance with claim 7 wherein said liner includes openings allowing air to pass in and out of said structures.

9. An orthopaedic support as defined in claim 1, wherein said pad further

comprises a plurality of fingers extending from said pad to said outer shell.

10. An orthopaedic support as defined in claim 9, wherein said fingers are integrally molded with said pad.

11. An orthopaedic support as defined in claim 9, wherein some of said fingers have a different length than others of said fingers.

12. An orthopaedic support as defined in claim 11, wherein said support has a malleolar region that is adapted to be placed against a malleolus of an ankle, said malleolar region having fingers of a greater length than fingers in other regions of said support.

13. An orthopaedic support for comfortably supporting a select area of the anatomy, said support comprising:

a substantially rigid shell; and

an injection molded resilient pad between said shell and the anatomy of the user, said pad configured with geometric shaped cells providing cushioning and support;

wherein said cells comprise walls, the structure of said walls providing cushioning support for the select area of the anatomy even without inflating the cells with air or otherwise filling said cells with liquid, gel and the like.

14. An orthopaedic support as defined in claim 13 further comprising an overmold molded onto said shell, said pad being connected to said overmold.

15. An orthopaedic support as defined in claim 13 wherein said pad is a bladder having a plurality of cells having cushioning geometric shapes and protrusions, each cell with predetermined size, depth, and wall thickness providing varying levels of localized support and cushion in different areas of said support.

16. An orthopaedic support as defined in claim 15 wherein said geometric shapes for said bladder are selected from the group consisting of ribs, cylinders, honeycomb, and regular and irregular polygons.

17. An orthopaedic support as defined in claim 15 wherein channels are provided between said cells for allowing a fluid to pass between and among said cells, creating a massaging effect on the ankle and promoting blood flow.

18. An orthopaedic support as defined in claim 17 wherein channels are provided through an outer wall of said pad to at least one of said cells to allow water to pass between and among said cells for hot and cold therapies.

19. An orthopaedic support as defined in claim 17 wherein said support further comprises inlet and outlet valves for allowing entry and removal of air and liquids.

20. An orthopaedic support as defined in claim 13 wherein said pad further comprises a foam core for softer inner cushion.

21. An orthopaedic support as defined in claim 13 wherein a co-molded lip around said shell and around said pad seals said pad such that air is trapped between said pad and said shell, creating a bladder with air cushion.

22. An orthopaedic support as defined in claim 13 wherein said pad is molded directly onto said shell as channels, domes, and other supportive geometrical shapes to cushion and to support the anatomy.

23. An orthopaedic support as defined in claim 13 wherein said pad includes a plurality of fingers extending from said pad to said shell.

24. An orthopaedic support comprising:

a substantially rigid shell formed to fit a limb of a user;

an injection molded pad for cushioning the shell to the limb;

said injection molded pad being integrally molded in a single molding step.

25. An orthopaedic support as defined in claim 24 wherein said pad includes interconnected cells, and further comprising a heel bladder fluidically coupled to said pad for varying the pressure exerted by said pad on the limb of the user.

26. An orthopaedic support pad as defined in claim 24 wherein said pad is a bladder having geometrically shaped cells to provide differing levels of localized cushioning and a plurality of channels molded between said cells to allow air and fluid to pass between said cells.

27. An orthopaedic support pad as defined in claim 26 further comprising fluid inlets and outlets to allow entry and removal of fluid from said pad for hot and cold therapy.

28. An orthopaedic support as defined in claim 26 wherein at least one cell defines a closed space forming an internal bladder.

29. An orthopaedic support as defined in claim 24 wherein said shell further comprises a shell frame and a shell core which is removably mounted within said shell.

30. An orthopaedic support as defined in claim 24 wherein a breathable liner covers said pad.

31. An orthopadic support as defined in claim 24 wherein said pad includes a plurality of integrally-molded fingers extending from said pad to said shell.

32. An orthopaedic support as defined in claim 24 further comprising an overmold molded onto said shell.

33. An orthopaedic support for comfortably supporting the ankle comprising:

an ankle support formed for fitting about the lower leg, having appropriate configuration to support the ankle;

said ankle support comprising a substantially rigid outer shell and a molded pad for cushioning;

said pad having an inner surface and an outer layer, said inner surface including resilient material having cells therein for providing resilient support to the ankle; and

said pad being bonded to said outer shell;

wherein said outer shell has at least one opening to allow air to escape from space in between said outer shell and said pad, said cells providing resilient support to the ankle from the structure of the cells even without being filled with air, liquid, gel and the like.

34. An orthopaedic support as defined in claim 33 wherein at least some of said air spaces are filled with foam for cushioning.

35. An orthopaedic support as defined in claim 34 wherein said foam surrounds but not covers the malleolus.

36. An orthopaedic support as defined in claim 33 wherein said pad includes a plurality of fingers extending from said pad toward said shell.

37. An orthopaedic support as defined in claim 33 further comprising an overmold molded onto said shell.

38. An orthopaedic support as defined in claim 37 wherein said pad is bonded to said overmold.

39. An orthopaedic support as defined in claim 38 wherein said overmold includes a ridge extending about the periphery of the overmold, said pad having an outer edge that engages with said ridge.

40. An orthopaedic support as defined in claim 33 wherein said pad includes a plurality of air holes to prevent formation of a bladder between said pad and said shell.

41. An orthopaedic support as defined in claim 33 wherein said pad has a non-uniform skin thickness, said pad having at least one region having skin that is thicker than at least one other region, in order to improve the function of the support.

42. An orthopaedic support comprising:

a flexible, molded outer shell having a first surface and a second surface, said first surface having an indentation therein; and at least one insert comprising a material that is relatively stiffer than said outer shell;

said support having a first mode in which said insert is removably secured within said indentation in said outer shell to stiffen the support, and a second mode in which said insert is removed from said indentation in said outer shell to make said support more flexible relative to said first mode.

43. An orthopaedic support as defined in claim 42, wherein said insert and said outer shell are adapted such that said insert is securable into the indentation in said outer shell by snap fit.

44. An orthopaedic support as defined in claim 42 further comprising a molded pad bonded to said shell, said pad having a substantially continuous surface and having a plurality of molded structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, said substantially continuous surface of said pad being adapted to be placed against a portion of the anatomy to be supported.

45. An orthopaedic support comprising:

a flexible, molded outer shell; and

at least one auxiliary member comprising a material that is relatively stiffer than said outer shell;

said support having a first mode in which said auxiliary member is removably secured to said outer shell to stiffen the support, and a second mode in which said insert is removed from said support to make said support more flexible relative to said first mode.

46. An orthopaedic support as defined in claim 45 further comprising a plurality of different interchangeable auxiliary members, each having a different stiffness, wherein a user may select a particular member depending on the stiffness desired.

47. An orthopaedic support for comfortably supporting the ankle of a wearer,

comprising:

an outer shell formed for fitting about the lower leg of the wearer;

a molded pad bonded to said shell;

said pad having a plurality of molded structures in between said pad and said shell to provide cushioning support for the wearer;

wherein said molded structures comprise walls, the structure of said walls providing cushioning support for the select area of the anatomy without inflating said structures with air or otherwise filling said structures with liquid, gel and the like.

48. An orthopaedic support for comfortably supporting a select area of the anatomy, said support comprising:

a substantially rigid shell; and

an injection molded resilient pad between said shell and the anatomy of the user, said pad being configured with geometric shaped cells providing cushioning and support;

said pad being bonded to said shell to form a fluid-filled bladder.

49. An orthopaedic support as defined in claim 48, further comprising a molded pad bonded to said shell, said pad having a substantially continuous surface and having a plurality of molded structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, said substantially continuous surface of said pad being adapted to be placed against a portion of the anatomy to be supported.

50. An orthopaedic support for comfortably supporting the ankle of a wearer, comprising:

an outer shell formed for fitting about the lower leg of the wearer;

a molded pad bonded to said shell;

said pad having a surface; and

said pad having a plurality of molded structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, at least some of said structures having a different dimension than others of said structures;

wherein said pad further comprises a plurality of fingers extending from said pad to said outer shell;

some of said fingers having a different length than others of said fingers; and

said support having a malleolar region that is adapted to be placed against a malleolus of an ankle, said malleolar region having fingers of a greater length than fingers in other regions of said support.

51. An orthopaedic support for comfortably supporting a select area of the anatomy, said support comprising:

a substantially rigid shell; and

an injection molded resilient pad between said shell and the anatomy of the user, said pad configured with geometric shaped cells providing cushioning and support;

wherein said pad is a bladder having a plurality of cells having cushioning geometric shapes and protrusions, each cell with predetermined size, depth, and wall thickness providing varying levels of localized support and cushion in different areas of said support;

wherein channels are provided between said cells for allowing a fluid to pass between and among said cells, creating a massaging effect on the ankle and promoting blood flow; and

wherein channels are provided through an outer wall of said pad to at least one of said cells for allowing a fluid to flow into said pad for hot and cold therapies.

52. An orthopaedic support comprising:

a substantially rigid shell formed to fit a limb of a user;

an injection molded pad for cushioning the shell to the limb;

said injection molded pad being integrally molded in a single molding step;

wherein said pad is a bladder having geometrically shaped cells to provide differing levels of localized cushioning and a plurality of channels molded between said cells to allow air and fluid to pass between said cells;

wherein at least one cell defines a closed space forming an internal bladder.

53. An orthopaedic support comprising:

a substantially rigid shell formed to fit a limb of a user;

an injection molded pad for cushioning the shell to the limb;

said injection molded pad being integrally molded in a single molding step;

wherein said shell further comprises a shell frame and a shell core which is removably mounted within said shell.

54. An orthopaedic support for comfortably supporting the ankle comprising:

an ankle support formed for fitting about the lower leg, having appropriate configuration to support the ankle;

said ankle support comprising a substantially rigid outer shell and a molded pad for cushioning;

said pad having an inner surface and an outer layer, said inner surface including resilient material having cells therein for providing resilient support to the ankle; and

said pad being bonded to said outer shell;

wherein said outer shell has at least one opening to allow air to escape from space in between said outer shell and said pad, said cells providing resilient support to the ankle from the structure of the cells even without being filled with air;

wherein at least some of said air spaces are filled with foam for cushioning; and

wherein said foam surrounds but not covers the malleolus.

55. An orthopaedic support for comfortably supporting the ankle comprising:

an ankle support formed for fitting about the lower leg, having appropriate configuration to support the ankle;

said ankle support comprising a substantially rigid outer shell and a molded pad for cushioning;

said pad having an inner surface and an outer layer, said inner surface including resilient material having cells therein for providing resilient support to the ankle; and

said pad being bonded to said outer shell;

wherein said outer shell has at least one opening to allow air to escape from space in between said outer shell and said pad, said cells providing resilient support to the ankle from the structure of the cells even without being filled with air;

wherein said orthopaedic support further comprises an overmold molded onto said shell;

wherein said pad is bonded to said overmold; and

wherein said overmold includes a ridge extending about the periphery of the overmold, said pad having an outer edge that engages with said ridge.

56. An orthopaedic support for comfortably supporting the ankle comprising:

an ankle support formed for fitting about the lower leg, having appropriate configuration to support the ankle;

said ankle support comprising a substantially rigid outer shell and a molded pad for cushioning;

said pad having an inner surface and an outer layer, said inner surface including resilient material having cells therein for providing resilient support to the ankle; and

said pad being bonded to said outer shell;

wherein said outer shell has at least one opening to allow air to escape from space in between said outer shell and said pad, said cells providing resilient support to the ankle from the structure of the cells even without being filled with air; and

wherein said pad has a non-uniform skin thickness, said pad having at least one region having skin that is thicker than at least one other region, in order to improve the function of the support.

57. An orthopaedic support comprising:

a flexible, molded outer shell having a first surface and a second surface, said first surface having an indentation therein; and at least one insert comprising a material that is relatively stiffer than said outer shell;

said support having a first mode in which said insert is removably secured within said indentation to stiffen the support, and a second mode in which said insert is removed from said indentation to make said support more flexible relative to said first mode;

wherein said orthopaedic support further comprises a molded pad bonded to said shell, said pad having a substantially continuous surface and having a plurality of molded structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, said substantially continuous surface of said pad being adapted to be placed against a portion of the anatomy to be supported.

58. An orthopaedic support comprising:

a flexible, molded outer shell; and

a plurality of different interchangeable auxiliary members, at least one of said auxiliary members comprising a material that is relatively stiffer than said outer shell;

said support having a first mode in which at least one of said auxiliary member is removably secured to said outer shell to stiffen the support, and a second mode in which said at least one insert is removed from said support to make said support more flexible relative to said first mode;

wherein a user may select a particular member depending on the stiffness desired.

COMFORTABLE ORTHOPAEDIC SUPPORT AND THE METHOD OF MAKING THE SAME

ABSTRACT

An improved comfortable ankle support is constructed using a molded pad (110) and a rigid shell (112). The pad (110) and the shell (112) may be sealed together to form a bladder-pad cushion for comfort. The internal structure of the pad is molded to include geometrically shaped cells of various size, shape and thickness to provide differing levels of localized comfort. The introduction of differing geometrically shaped cells, such as honeycomb structured cells (152), provide localized comfort to the user of the ankle support. The pad may be made from a thermoplastic elastomer (TPE) which, unlike foam or other previously proposed materials, is very springlike and resists compression sets. The pad may be embedded with foam to increase the cushioning effect. The pad may include integrally-molded fingers (321) extending to the shell. The fingers may have different lengths in one or more regions, in order to increase the cushioning effect in a particular region. The skin of the pad may be thicker in at least one region than in other regions, in order to stiffen the pad in the thicker-skinned region. The pad/shell combination may form a sealed bladder, and a pneumatic pump may be provided in conjunction with the shell so that the user can inflate the bladder.

FIG. 1

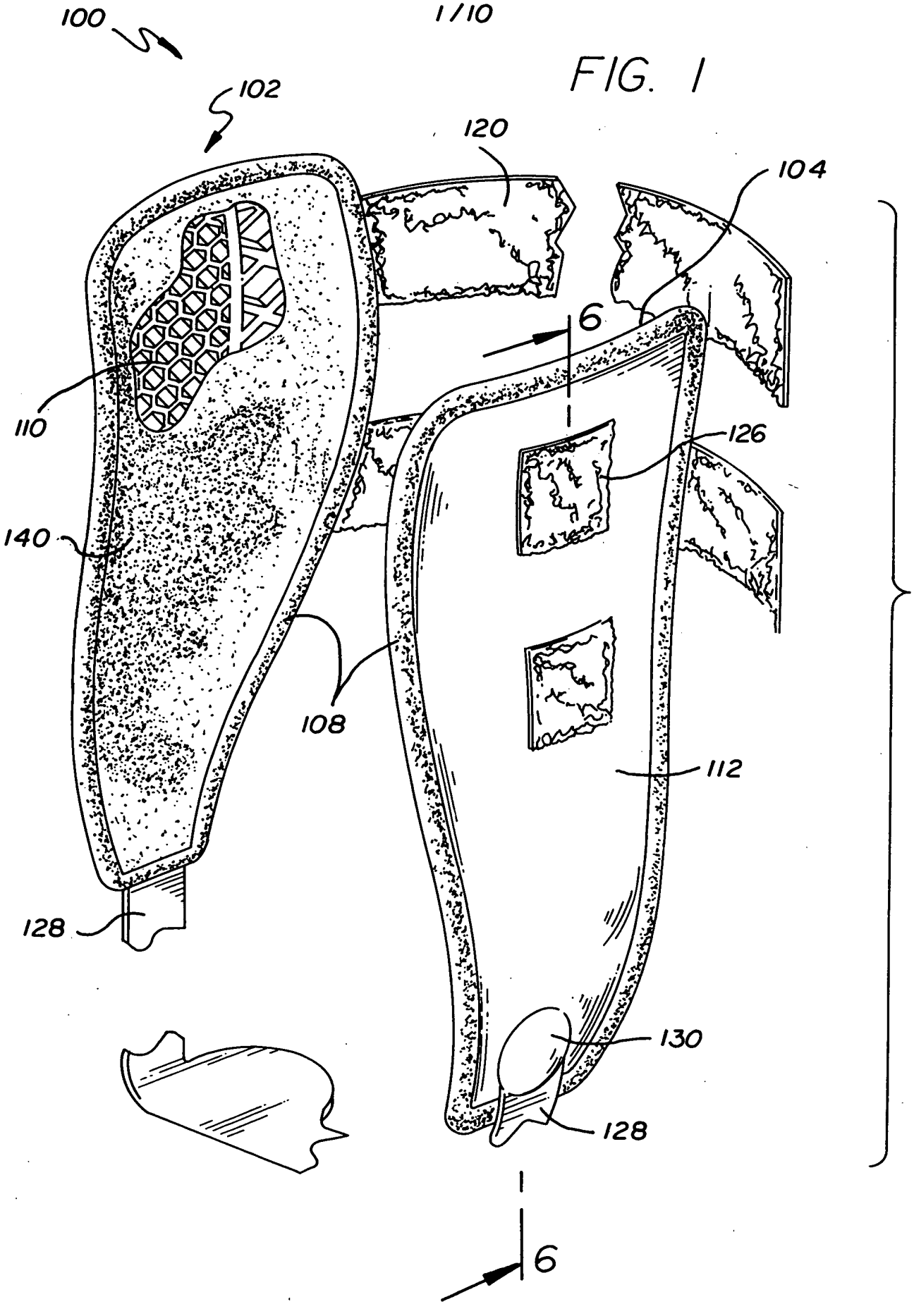


FIG. 2

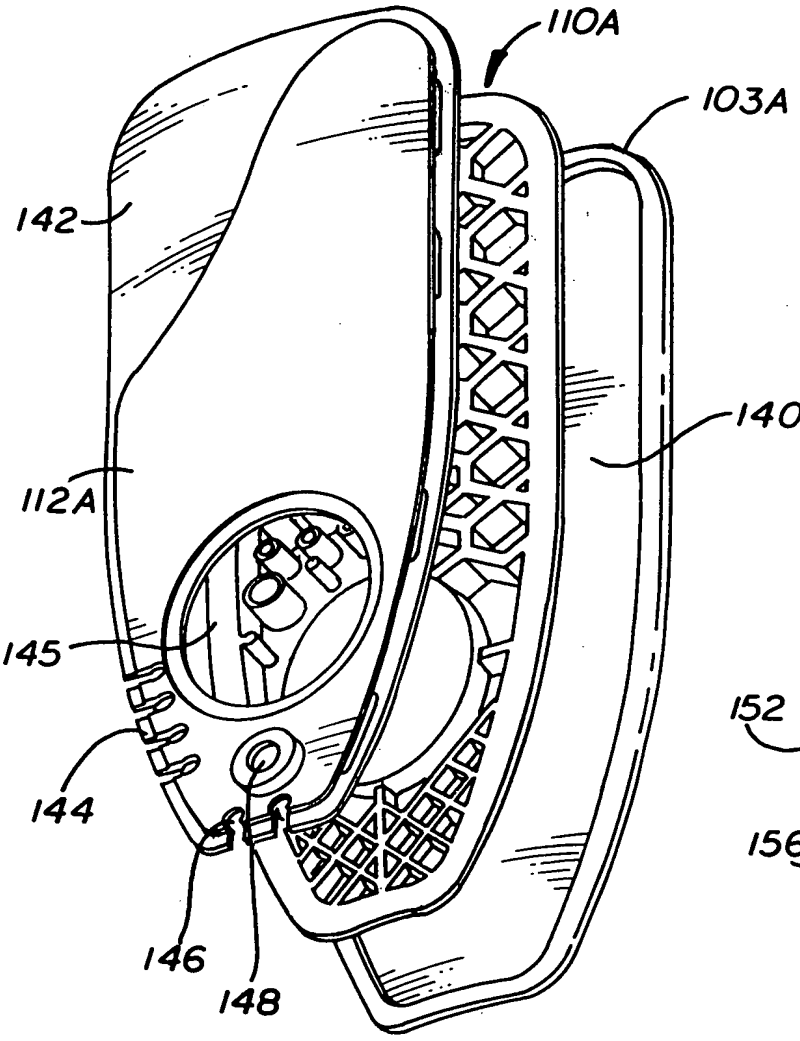


FIG. 3

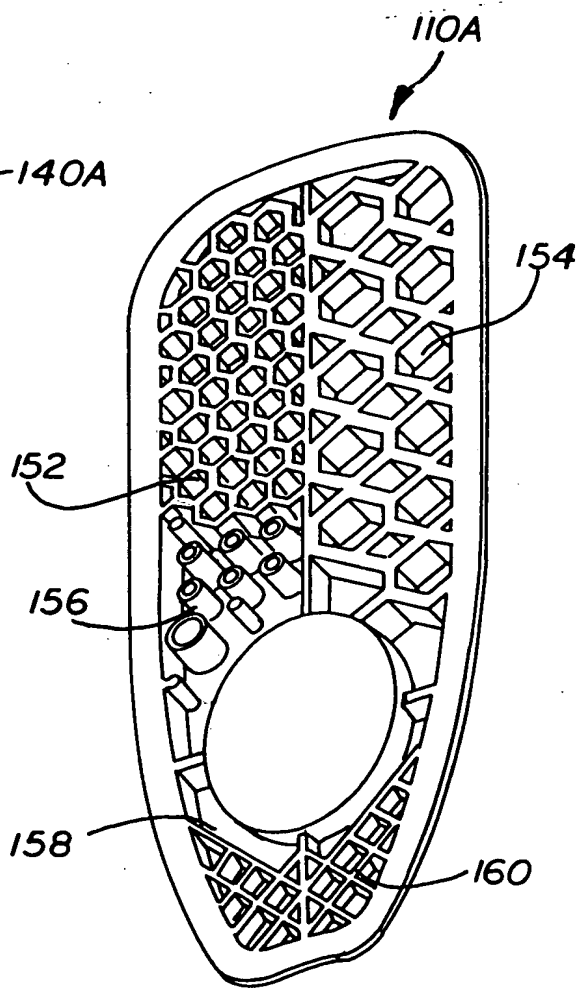


FIG. 5

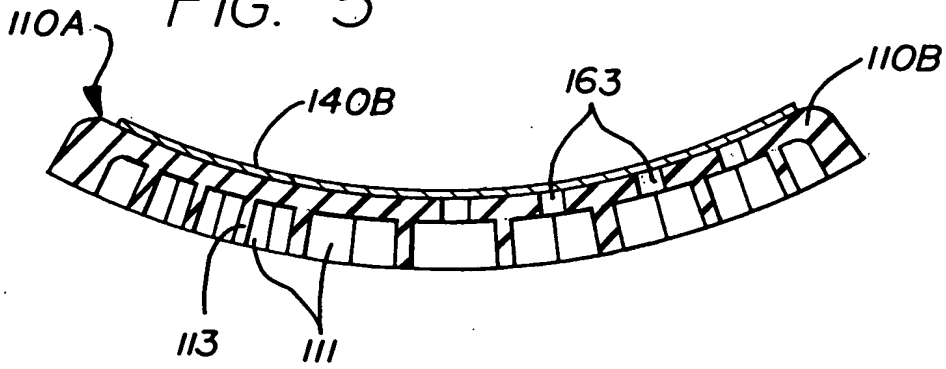
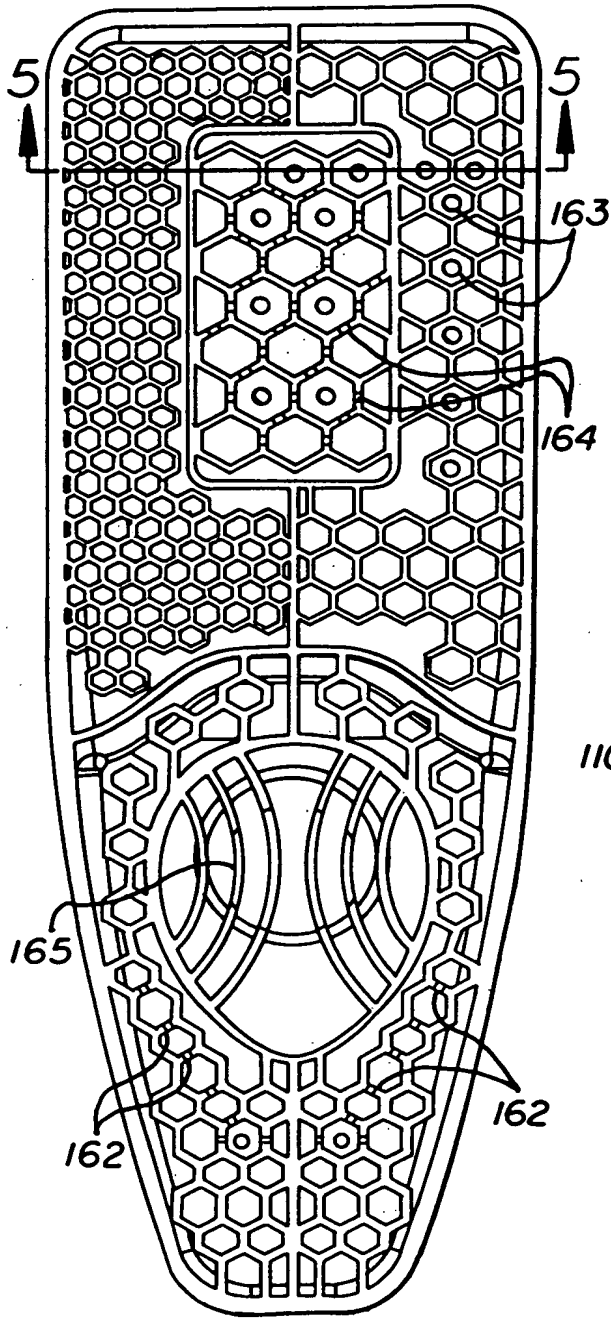


FIG. 4



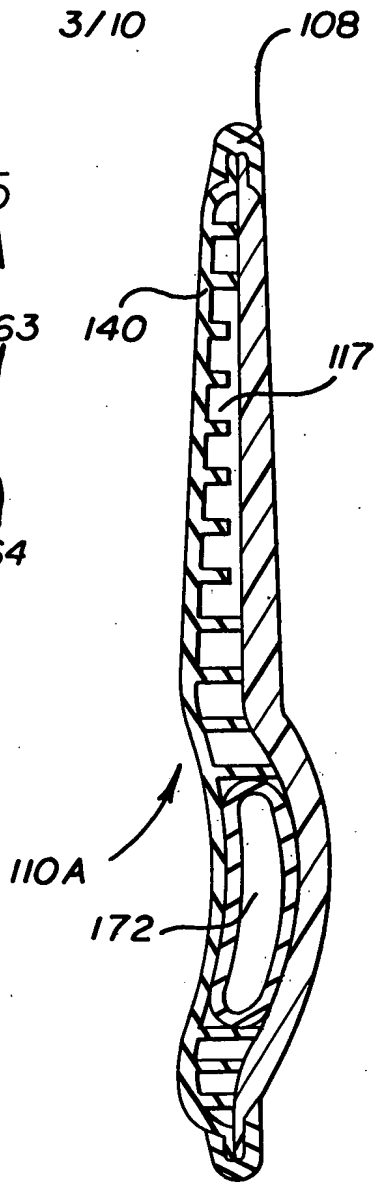


FIG. 6

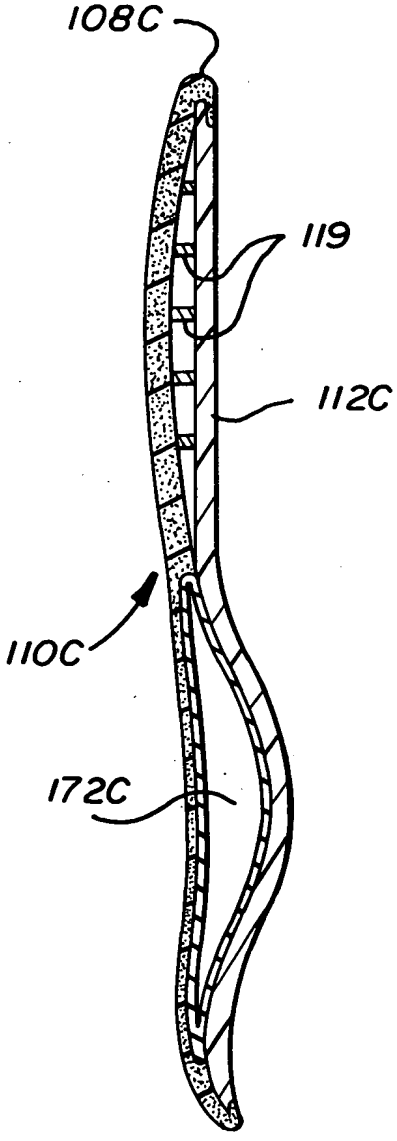


FIG. 7

FIG. 8

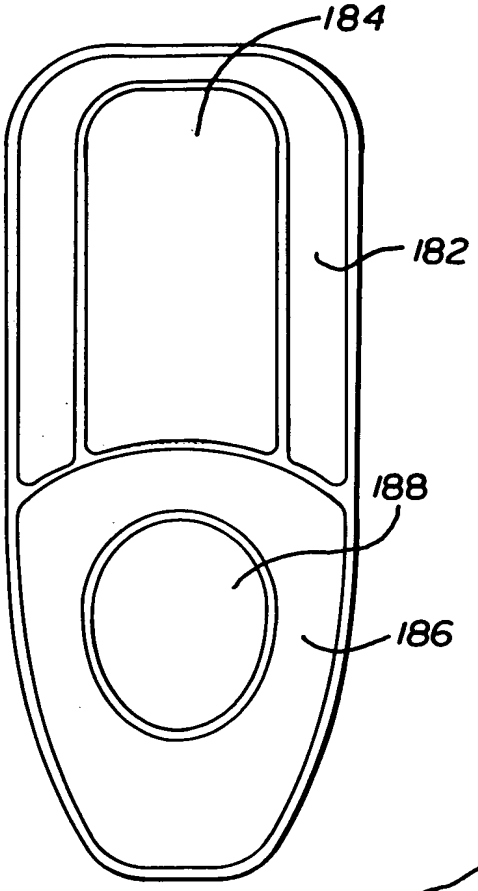


FIG. 10

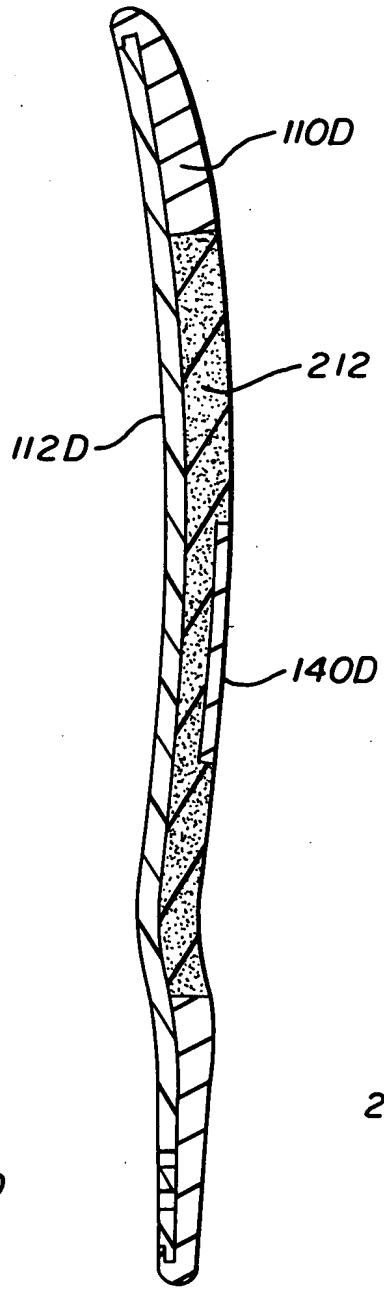
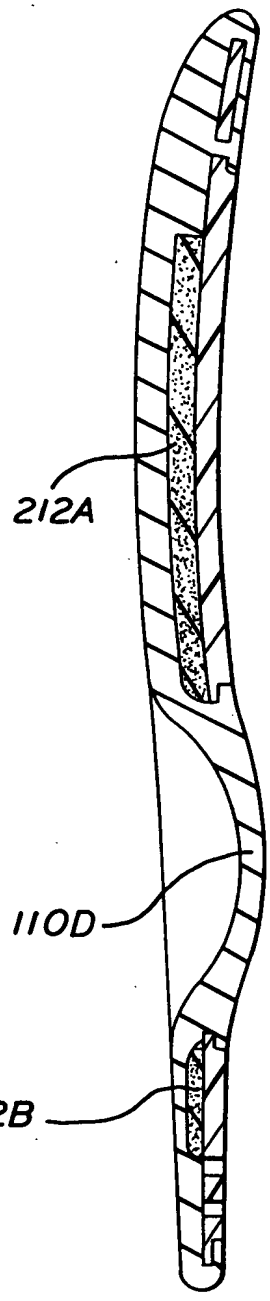


FIG. 11



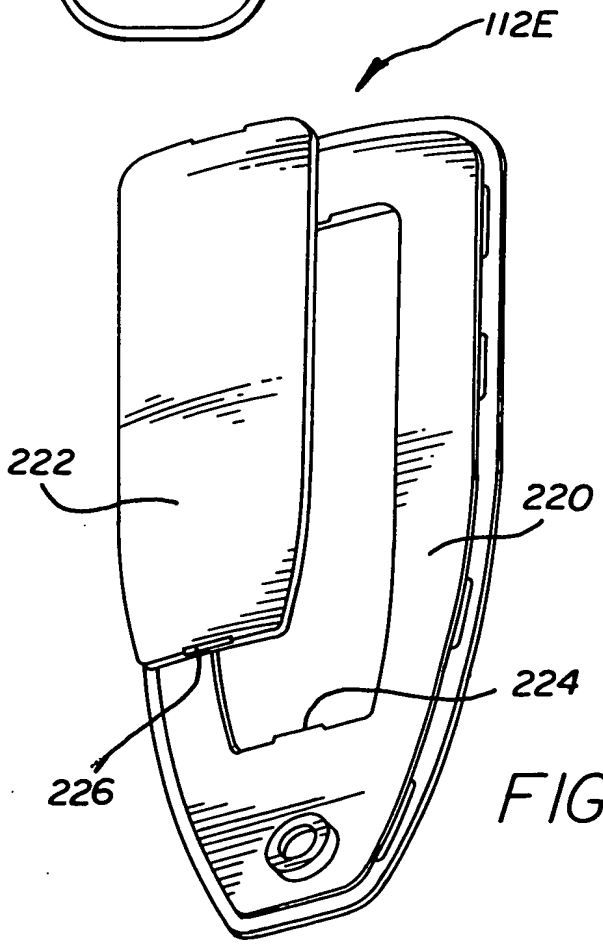
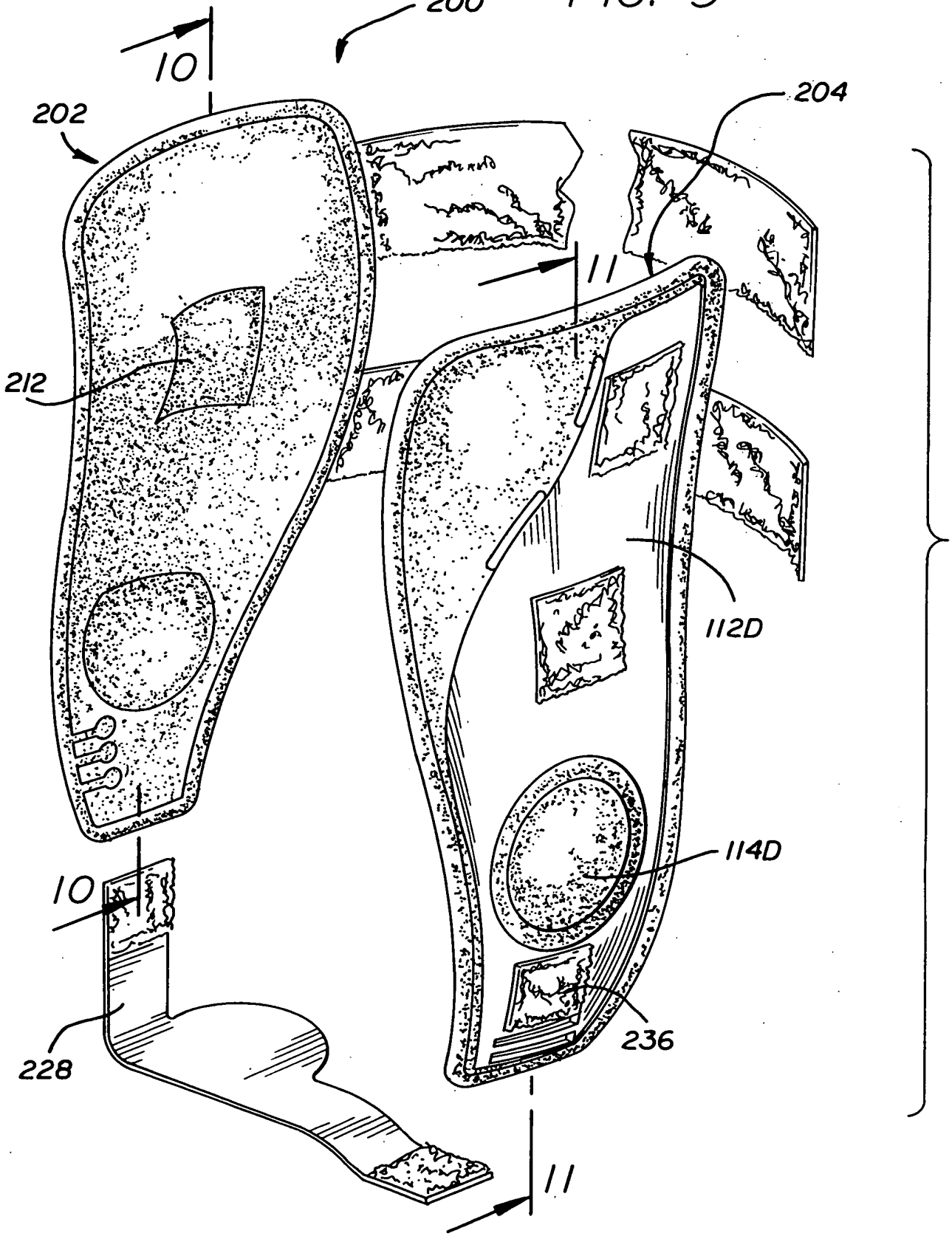


FIG. 12

FIG. 9



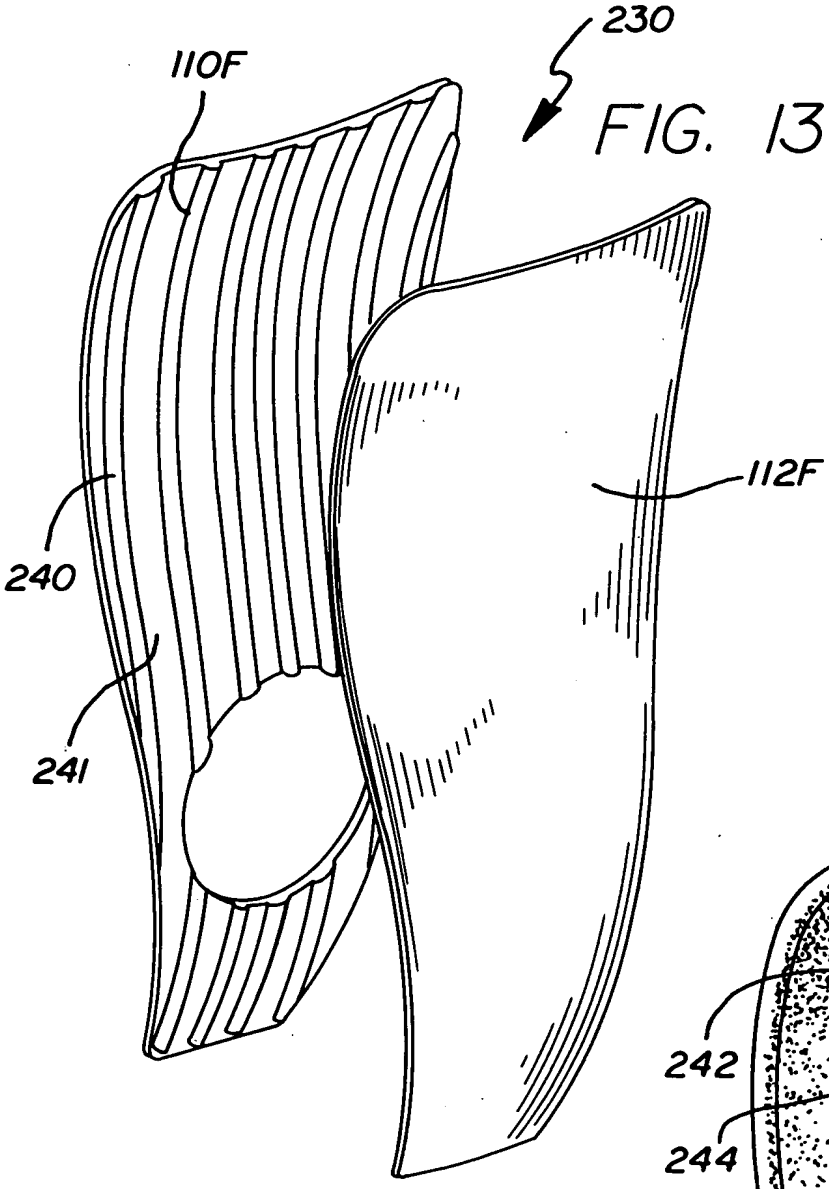


FIG. 13

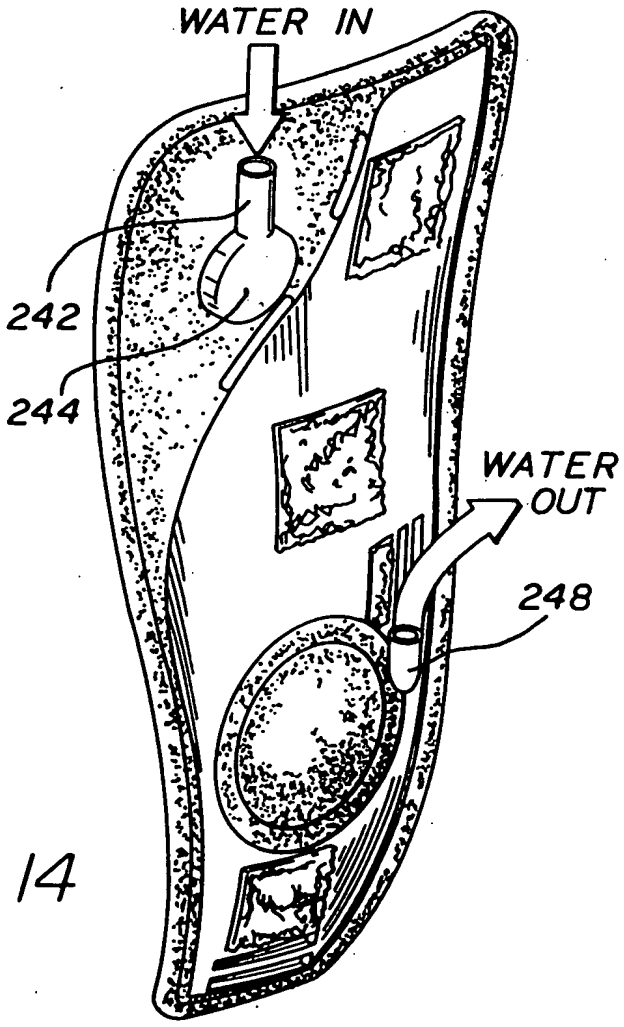


FIG. 14

FIG. 15

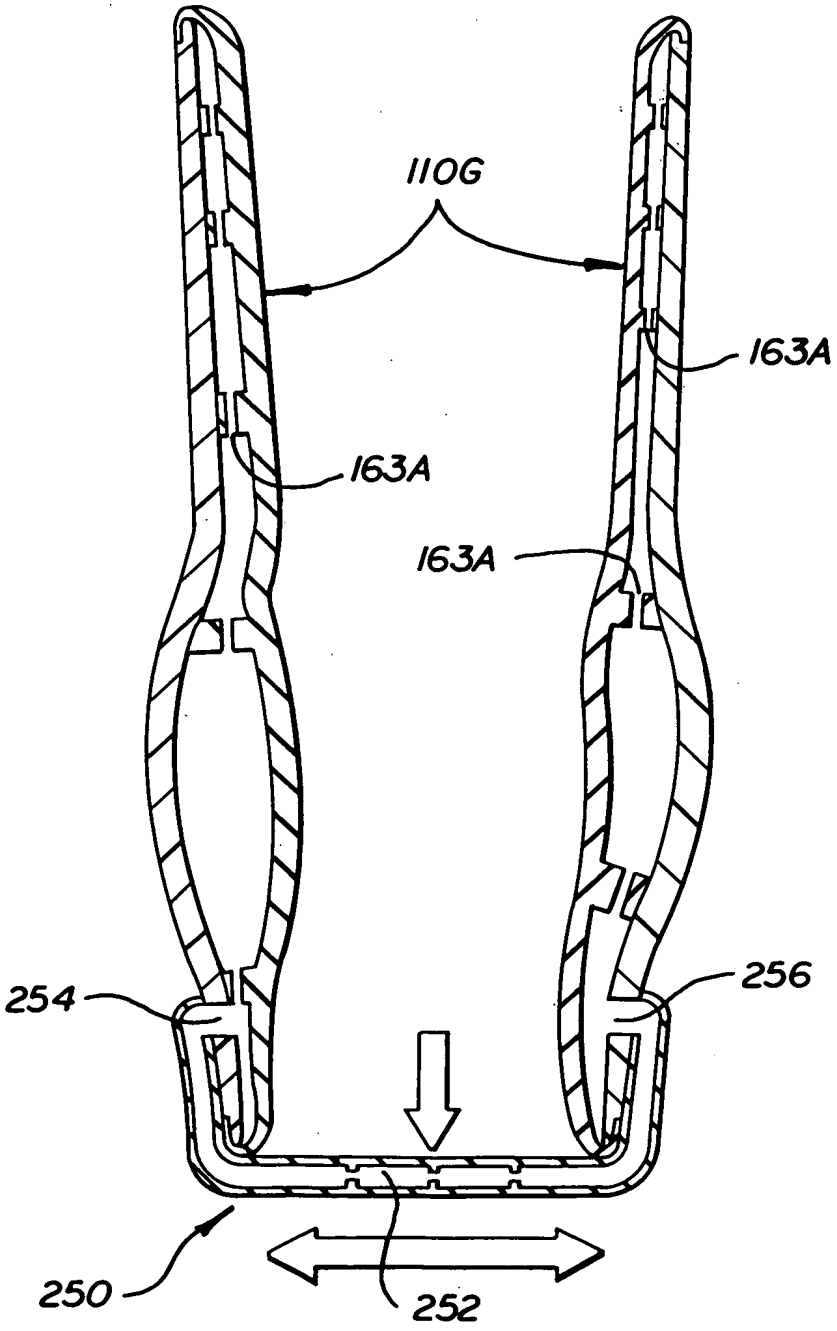


FIG. 16

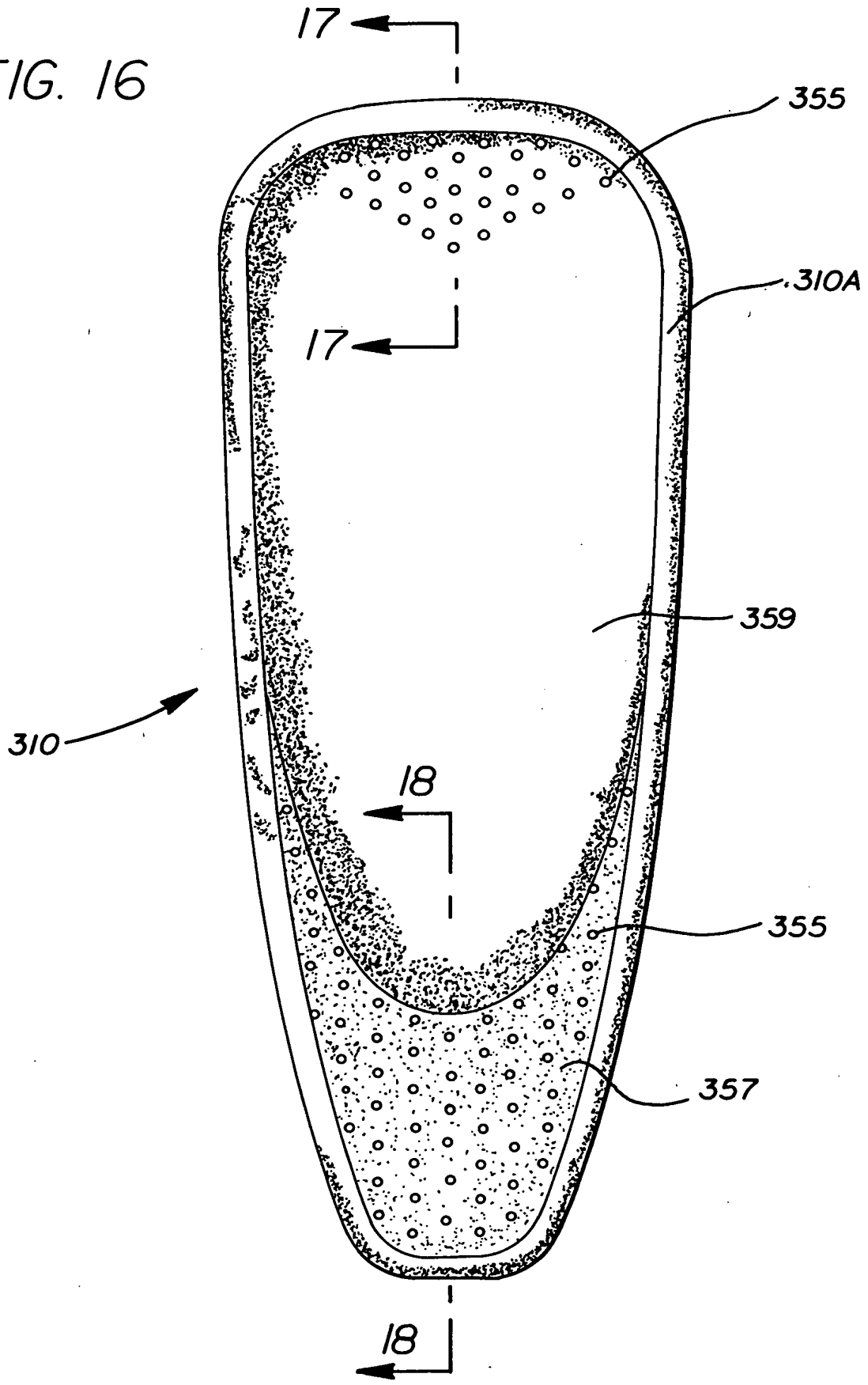


FIG. 17

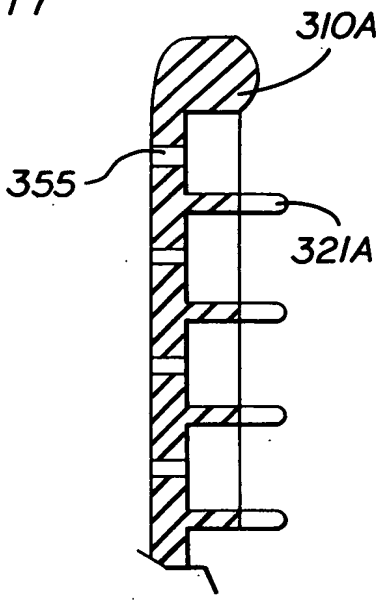


FIG. 18

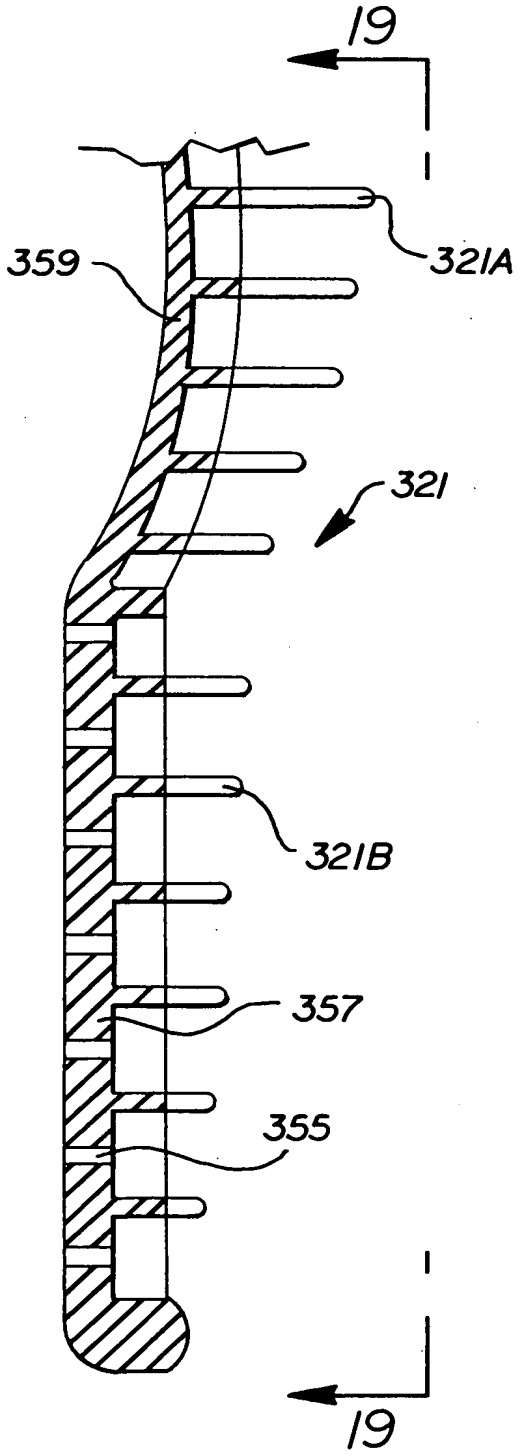


FIG. 19

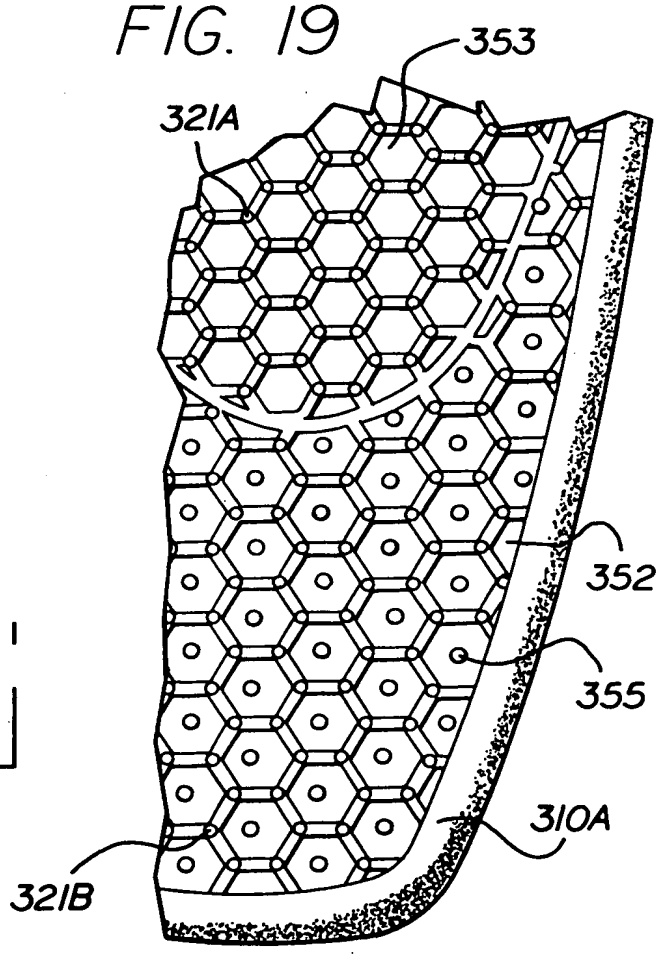
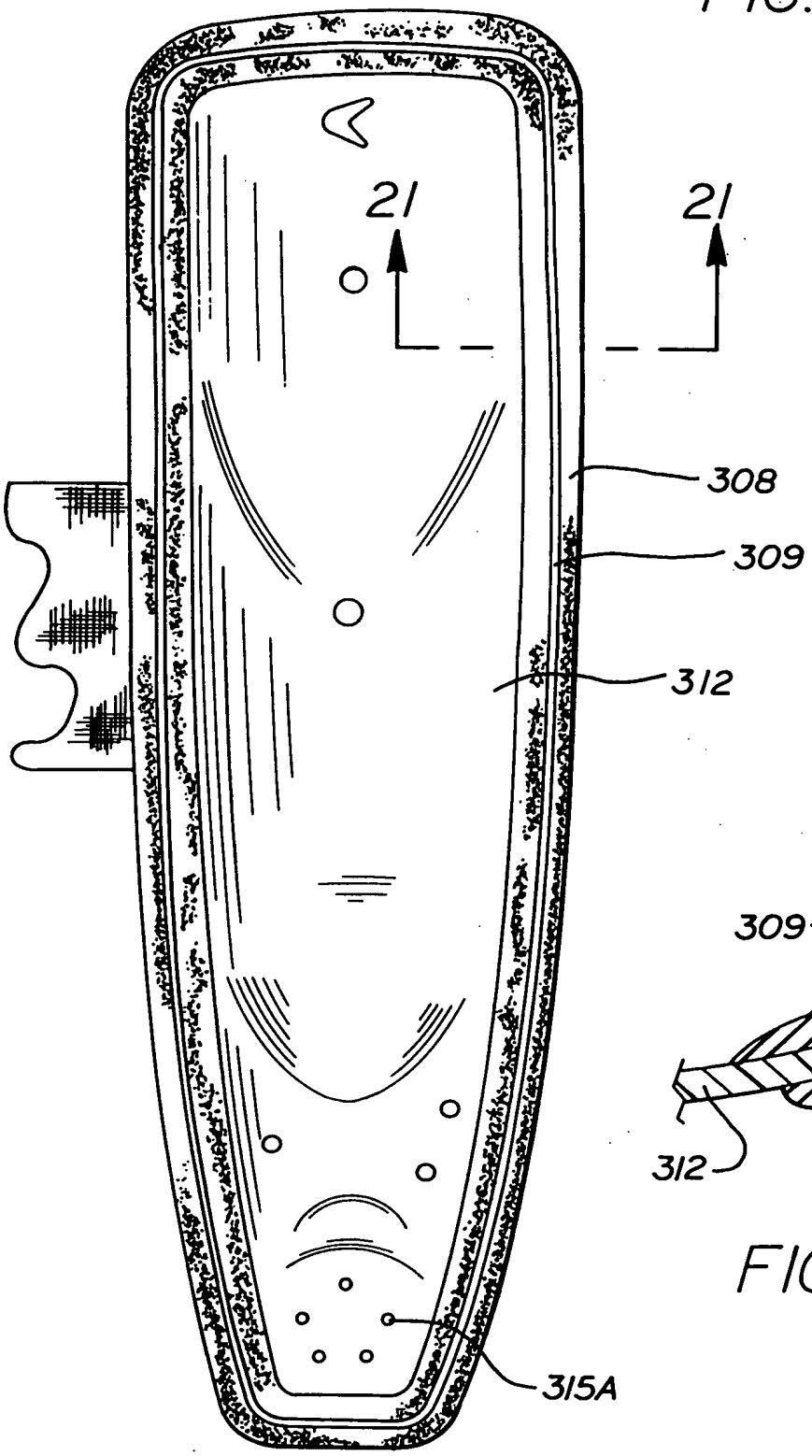


FIG. 20



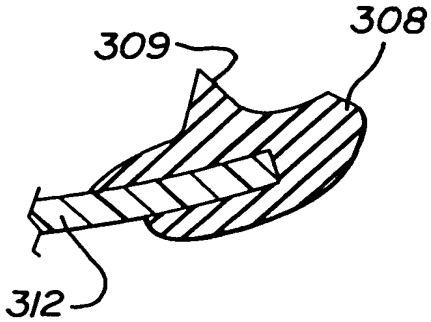


FIG. 21

CLAIMS

WE CLAIM:

1. An orthopaedic support for comfortably supporting the ankle of a wearer, comprising:

an outer shell formed for fitting about the lower leg of the wearer;

a molded pad bonded to said shell;

said pad having a surface; and

said pad having a plurality of molded structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, at least some of said structures having a different dimension than others of said structures.

2. An orthopaedic support in accordance with 1 wherein an overmold substantially surrounds said pad and said shell substantially sealing together said orthopaedic support.

3. An orthopedic support as defined in claim 1 further comprising an overmold molded onto said shell, said pad being bonded to said overmold.

4. An orthopaedic support as defined in claim 1 further comprising means for securing said ankle support around the lower leg; and a heel strap for securing said orthopaedic support.

5. An orthopaedic support as defined in claim 1 wherein said pad bonded to said shell forms a fluid-filled bladder.

6. An orthopaedic support as defined in claim 1 wherein an inner liner of cloth is secured to said pad on the surface of said pad facing the lower leg of the user.

7. An orthopaedic support as defined in claim 6 wherein said liner is integrated with said pad.

8. An orthopaedic support in accordance with claim 7 wherein said liner includes openings allowing air to pass in and out of said structures.

9. An orthopaedic support as defined in claim 1, wherein said pad further comprises a plurality of fingers extending from said pad to said outer shell.

10. An orthopaedic support as defined in claim 9, wherein said fingers are integrally molded with said pad.

11. An orthopaedic support as defined in claim 9, wherein some of said fingers have a different length than others of said fingers.

12. An orthopaedic support as defined in claim 11, wherein said support has a malleolar region that is adapted to be placed against a malleolus of an ankle, said malleolar region having fingers of a greater length than fingers in other regions of said support.

13. An orthopaedic support for comfortably supporting a select area of the anatomy, said support comprising:

a substantially rigid shell; and

an injection molded resilient pad between said shell and the anatomy of the user, said pad configured with geometric shaped cells providing cushioning and support.

14. An orthopaedic support as defined in claim 13 further comprising an overmold molded onto said shell, said pad being connected to said overmold.

15. An orthopaedic support as defined in claim 13 wherein said pad is a bladder having a plurality of cells having cushioning geometric shapes and protrusions, each cell with predetermined size, depth, and wall thickness providing varying levels of localized support and cushion in different areas of said support.

16. An orthopaedic support as defined in claim 15 wherein said geometric shapes for said bladder are selected from the group consisting of ribs, cylinders, honeycomb, and regular and irregular polygons.

17. An orthopaedic support as defined in claim 15 wherein channels are provided between said cells for allowing a fluid to pass between and among said cells, creating a massaging effect on the ankle and promoting blood flow.

18. An orthopaedic support as defined in claim 17 wherein channels are provided through an outer wall of said pad to at least one of said cells to allow water to pass between and among said cells for hot and cold therapies.

19. An orthopaedic support as defined in claim 17 wherein said support further comprises inlet and outlet valves for allowing entry and removal of air and liquids.

20. An orthopaedic support as defined in claim 13 wherein said pad further comprises a foam core for softer inner cushion.

21. An orthopaedic support as defined in claim 13 wherein a co-molded lip around said shell and around said pad seals said pad such that air is trapped between said pad and said shell, creating a bladder with air cushion.

22. An orthopaedic support as defined in claim 13 wherein said pad is molded directly onto said shell as channels, domes, and other supportive geometrical shapes to cushion and to support the anatomy.

23. An orthopadic support as defined in claim 13 wherein said pad includes a plurality of fingers extending from said pad to said shell.

24. An orthopaedic support comprising:

a substantially rigid shell formed to fit a limb of a user;

an injection molded pad for cushioning the shell to the limb;

said injection molded pad being integrally molded in a single molding step.

25. An orthopaedic support as defined in claim 24 wherein said pad includes interconnected cells, and further comprising a heel bladder fluidically coupled to said pad for varying the pressure exerted by said pad on the limb of the user.

26. An orthopaedic support pad as defined in claim 24 wherein said pad is a bladder having geometrically shaped cells to provide differing levels of localized cushioning and a plurality of channels molded between said cells to allow air and fluid to pass between said cells.

27. An orthopaedic support pad as defined in claim 26 further comprising fluid inlets and outlets to allow entry and removal of fluid from said pad for hot and cold therapy.

28. An orthopaedic support as defined in claim 26 wherein at least one cell defines a closed space forming an internal bladder.

29. An orthopaedic support as defined in claim 24 wherein said shell further comprises a shell frame and a shell core which is removably mounted within said shell.

30. An orthopaedic support as defined in claim 24 wherein a breathable liner covers said pad.

31. An orthopadic support as defined in claim 24 wherein said pad includes a plurality of integrally-molded fingers extending from said pad to said shell.

32. An orthopaedic support as defined in claim 24 further comprising an overmold molded onto said shell.

33. An orthopaedic support for comfortably supporting the ankle comprising:

an ankle support formed for fitting about the lower leg, having appropriate configuration to support the ankle;

said ankle support comprising a substantially rigid outer shell and a molded pad for cushioning;

said pad having an inner surface and an outer layer, said inner surface including resilient material having cells therein for providing resilient support to the ankle; and

said pad being bonded to said outer shell;

wherein said outer shell has at least one opening to allow air to escape from space in between said outer shell and said pad, said cells providing resilient support to the ankle from the structure of the cells even without being filled with air.

34. An orthopaedic support as defined in claim 33 wherein at least some of said air spaces are filled with foam for cushioning.

35. An orthopaedic support as defined in claim 34 wherein said foam surrounds but not covers the malleolus.

36. An orthopaedic support as defined in claim 33 wherein said pad includes a plurality of fingers extending from said pad toward said shell.

37. An orthopaedic support as defined in claim 33 further comprising an overmold molded onto said shell.

38. An orthopaedic support as defined in claim 37 wherein said pad is bonded to said overmold.

39. An orthopaedic support as defined in claim 38 wherein said overmold includes a ridge extending about the periphery of the overmold, said pad having an outer edge that engages with said ridge.

40. An orthopaedic support as defined in claim 33 wherein said pad includes a plurality of air holes to prevent formation of a bladder between said pad and said shell.

41. An orthopaedic support as defined in claim 33 wherein said pad has a non-uniform skin thickness, said pad having at least one region having skin that is thicker than at least one other region, in order to improve the function of the support.

42. An orthopaedic support comprising:

a flexible, molded outer shell having a first surface and a second surface, said first surface having an indentation therein; and at least one insert comprising a material that is relatively stiffer than said outer shell;

said support having a first mode in which said insert is removably secured within said indentation to stiffen the support, and a second mode in which said insert is removed from said indentation to make said support more flexible relative to said first mode.

43. An orthopaedic support as defined in claim 42, wherein said insert and said outer shell are adapted such that said insert is securable into the indentation in said outer shell by snap fit.

44. An orthopaedic support as defined in claim 42 further comprising a molded pad bonded to said shell, said pad having a substantially continuous surface and having a plurality of molded structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, said substantially continuous surface of said pad being adapted to be placed against a portion of the

anatomy to be supported.

45. An orthopaedic support comprising:

a flexible, molded outer shell; and

at least one auxilliary member comprising a material that is relatively stiffer than said outer shell;

said support having a first mode in which said auxilliary member is removably secured to said outer shell to stiffen the support, and a second mode in which said insert is removed from said support to make said support more flexible relative to said first mode.

46. An orthopaedic support as defined in claim 45 further comprising a plurality of different interchangeable auxilliary members, each having a different stiffness, wherein a user may select a particular member depending on the stiffness desired.

47. An orthopaedic support for comfortably supporting the ankle of a wearer, comprising:

an outer shell formed for fitting about the lower leg of the wearer;

a molded pad bonded to said shell;

said pad having a plurality of molded structures in between said pad and said shell to provide cushioning support for the wearer.

48. An orthopaedic support for comfortably supporting a select area of the anatomy, said support comprising:

a substantially rigid shell; and

an injection molded resilient pad between said shell and the anatomy of the user, said pad being configured with geometric shaped cells providing cushioning and support;

said pad being bonded to said shell to form a fluid-filled bladder.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: SCOTT R. HANSEN
OPPENHEIMER, POMS, SMITH
2029 CENTURY PARK EAST, SUITE 3800
LOS ANGELES, CALIFORNIA 90067

RECEIVED
NOV 14 1997

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 480032-213	Date of Mailing *(day/month/year)* 10 NOV 1997 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US97/15265	International filing date *(day/month/year)* 29 AUGUST 1997
Applicant ROYCE MEDICAL COMPANY	

1. [X] The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer DENISE POTHIER Telephone No. (703) 308-0993

Form PCT/ISA/220 (January 1994)*

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 480032-213	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US97/15265	International filing date *(day/month/year)* 29 AUGUST 1997	(Earliest) Priority Date *(day/month/year)* 29 AUGUST 1996
Applicant ROYCE MEDICAL COMPANY		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. [ ] **Certain claims were found unsearchable** (See Box I).

2. [ ] **Unity of invention is lacking** (See Box II).

3. [ ] The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
   - [ ] filed with the international application.
   - [ ] furnished by the applicant separately from the international application,
     - [ ] but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
   - [ ] transcribed by this Authority.

4. With regard to the **title**,
   - [X] the text is approved as submitted by the applicant.
   - [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,
   - [ ] the text is approved as submitted by the applicant.
   - [X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is:

   Figure No. 1
   - [ ] as suggested by the applicant.
   - [X] because the applicant failed to suggest a figure.
   - [ ] because this figure better characterizes the invention.
   - [ ] None of the figures.

International application No.
PCT/US97/15265

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The Abstract is too long (PCT Rule 8.1(b)). The Abstract must be less than 150 words, or 200 words when no figure is to be published.

NEW ABSTRACT

An ankle support (100) is constructed using a molded pad (110) and a rigid shell (112). The pad (110) and the shell (112) may be sealed together to form a bladder pad cushion. The internal structure of the pad (110) is molded to include geometrically shaped cells of various size, shape and thickness to provide differing levels of localized comfort to the user of the ankle support (100). The pad may be made from a thermoplastic elastomer (TPE) which is spring-like and resists compression sets. The pad may include integrally molded fingers extending to the shell. The fingers may have different lengths in one or more regions, in order to increase the cushioning effect in a particular region. The pad/shell combination may form a sealed bladder, and a pneumatic pump may be provided in conjunction with the shell so that the user can inflate the bladder.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/15265

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 5/00
US CL :602/23, 27, 62
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 2/16, 22, 455; 36/89, 90, 140; 128/882; 602/5, 14, 23, 27, 62, 65

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,366,439 A (PETERS) 22 November 1994, col. 8,lines 40-68, col. 9 lines 1-65, and col 10 lines 1-18.	1, 13, 15, 16, 18, 45 --- 2, 4, 6-8, 17, 22, 23, 33, 41
Y	US 5,445,602 A (GRIM et al.) 29 August 1995, col. 5 lines 1-6 and 60-66, and col. 7 lines 12-23.	2, 4, 6-8, 30, 33, 41

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 08 OCTOBER 1997	Date of mailing of the international search report 10 NOV 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer DENISE POTHIER Telephone No. (703) 308-0993

Form PCT/ISA/210 (second sheet)(July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/15265

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,007,111 A (ADAMS) 16 April 1991, col. 3 lines 42-59, col. 6 lines 21-36, and col. 7 lines 21-68.	1, 5, 9-11, 47 --- 17, 19, 22, 23, 26-28, 31, 42, 44
X --- Y	US 4,966,134 A (BREWER) 30 October 1990, col. 6, lines 5-68.	24 --- 26-28, 31, 42, 44
Y	US 4,977,891 A (GRIM) 18 December 1990, col. 3 lines 21-68, and col. 4 lines 52-54.	24, 25, 30
Y	US 5,496,610 A (LANDI et al.) 29 August 1995, col. 9 lines 3-20.	24, 30, 31, 47, 48
A	US 2,818,571 A (GRANT) 7 January 1958, entire document.	3, 14, 21, 32, 37-39
A	US 5,007,416 A (BURNS et al.) 16 Apr.il 1991, entire document.	20
A	US 4,730,610 A (GRAEBE) 15 March 1988, entire document.	1-48
A	US 5,288,286 A (DAVIS et al.), 22 February 1994, entire document.	1-48
A	US 5,403,265 A (BERGUER et al.) 04 April 1995, entire document.	1-48

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

HANSEN, Scott, R.
Oppenheimer Wolff & Donnelly L.L.P.
Suite 3800
2029 Century Park East
Los Angeles, CA 90067
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)
04 May 1998 (04.05.98)

Applicant's or agent's file reference
480032-213

IMPORTANT NOTIFICATION

International application No.
PCT/US97/15265

International filing date (day/month/year)
29 August 1997 (29.08.97)

1. The following indications appeared on record concerning:

[ ] the applicant [ ] the inventor [X] the agent [ ] the common representative

Name and Address
HANSEN, Scott, R.
Oppenheimer Poms Smith
Suite 3800
2029 Century Park East
Los Angeles, CA 90067
United States of America

State of Nationality | State of Residence

Telephone No.
(310) 788-5000

Facsimile No.
(310) 277-1297

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [X] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address
HANSEN, Scott, R.
Oppenheimer Wolff & Donnelly L.L.P.
Suite 3800
2029 Century Park East
Los Angeles, CA 90067
United States of America

State of Nationality | State of Residence

Telephone No.
(310) 788-5000

Facsimile No.
(310) 277-1297

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
N. Fischer

Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994)

002020514

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

United States Patent and Trademark Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 04 May 1998 (04.05.98)	
International application No. PCT/US97/15265	**Applicant's or agent's file reference** 480032-213
International filing date (day/month/year) 29 August 1997 (29.08.97)	**Priority date** (day/month/year) 29 August 1996 (29.08.96)
Applicant IGLESIAS, Joseph, M. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

30 March 1998 (30.03.98)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer N. Fischer
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: SCOTT R. HANSEN
OPPENHEIMER, POMS, SMITH
2029 CENTURY PARK EAST, SUITE 3800
LOS ANGELES, CALIFORNIA 90067

SRH

RECEIVED
DEC 04 1998
OPPENHEIMER

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing *(day/month/year)*	23 NOV 1998
Applicant's or agent's file reference 480032-213	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/US97/15265	29 AUGUST 1997	29 AUGUST 1996

Applicant
ROYCE MEDICAL COMPANY

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer DENISE POTHIER
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0993

Form PCT/IPEA/416 (July 1992)*

5

PATENT COOPERATION TREATY

REC'D 27 NOV 1998
WIPO PCT

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 480032-213	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US97/15265	International filing date *(day/month/year)* 29 AUGUST 1997	Priority date *(day/month/year)* 29 AUGUST 1996
International Patent Classification (IPC) or national classification and IPC IPC(6): A61F 5/00; and US Cl.: 602/23, 27, 62		
Applicant ROYCE MEDICAL COMPANY		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 12 sheets.

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [ ] Non-establishment of report with regard to novelty, inventive step or industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [X] Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30 MARCH 1998	06 OCTOBER 1998
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer DENISE POTHIER Telephone No. (703) 308-0993

Form PCT/IPEA/409 (cover sheet) (January 1994)★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US97/15265

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments)*:

☐ the international application as originally filed.

☒ the description, pages (See Attached) , as originally filed.
pages _____ , filed with the demand.
pages _____ , filed with the letter of _____.
pages _____ , filed with the letter of _____.

☒ the claims, Nos. (See Attached) , as originally filed.
Nos. _____ , as amended under Article 19.
Nos. _____ , filed with the demand.
Nos. _____ , filed with the letter of _____.
Nos. _____ , filed with the letter of _____.

☒ the drawings, sheets/~~fig~~ (See Attached) , as originally filed.
sheets/~~fig~~ _____ , filed with the demand.
sheets/~~fig~~ _____ , filed with the letter of _____.
sheets/~~fig~~ _____ , filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE.

☒ the claims, Nos. NONE.

☒ the drawings, sheets/~~fig~~ NONE.

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 STATEMENT

Novelty (N)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO
Inventive Step (IS)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO
Industrial Applicability (IA)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-4, 9, 10, 13-17, 21-23, 42 and 45 lack novelty under PCT Article 33(2) as being anticipated by Peters. Peters discloses in Figs. 12-15 in column 8 lines 40-68, and in column 9 lines 1-68 an orthopaedic support comprising an outer shell (68) formed for fitting about the leg of the wearer, a molded pad (66) bonded to the shell, the pad having a surface and a plurality of molded structures comprising walls to provide differing levels of cushioning support, at least some of the structures having a different dimension than others of the structure. The molded structure does provide, as disclosed in column 8, lines 44-48, some of cushioning even without inflating or otherwise filling the molded structure.

Claims 2 and 3, Peters discloses in Fig. 15, and in column 8 lines 40-68 an over-mold (the structure around the perimeter creating a seal) substantially surrounds the pad and the shell substantially sealing together the orthopaedic support. The over-mold is molded onto the shell, the pad bonded to the over-mold.

Claim 4, Peters discloses in Fig. 15 a means for securing (44)(46) the ankle support around the lower leg and a heel strap (10) for securing the orthopaedic support.

Claims 9 and 10, Peters discloses in Fig. 14 that the pad further comprises a plurality of fingers (some of the bubbles) extending from the pad to the outer shell and that the fingers are integrally molded with the pad.

Claim 13, Peters discloses in Figs. 12-15, and columns 4 and 5 lines 68, and 1-3 a substantially rigid shell and a resilient pad between the shell and the user configured with circular cells.

Claim 14, see above rejection of claim 2.

Claim 15, Peters discloses in Figs. 12-15, and in columns 8 and 9 lines 57-68, and 1-7 a pad that is a bladder having a plurality of geometric shaped cells of predetermined size that localize (Continued on Supplemental Sheet.)

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1, 13 and 33 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason:

Claim 1 line 12, the phrase "and the like" does not particulary point out what "the like" to air, liquid and gel would be.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

I. BASIS OF REPORT:

This report has been drawn on the basis of the description,
pages, 1-28, as originally filed.
pages, NONE, filed with the demand.
and additional amendments:
NONE

This report has been drawn on the basis of the claims,
numbers, none, as originally filed.
numbers, NONE, as amended under Article 19.
numbers, NONE, filed with the demand.
and additional amendments:
Claims 1-58, filed with the letter of 02 September 1998.

This report has been drawn on the basis of the drawings,
sheets, 1-10, as originally filed.
sheets, NONE, filed with the demand.
and additional amendments:
NONE

V. 1. REASONED STATEMENTS:
The report as to Novelty was positive (YES) with respect to claims 6-8, 12, 18-20, 25-41, 43, 44, 46, 50-58.
The report as to Novelty was negative (NO) with respect to claims 1-5, 9-11, 13-17, 21-24, 42, 45, 47-49.
The report as to Inventive Step was positive (YES) with respect to claims 12, 18, 28, 29, 35, 39, 41, 44, 46, 50-58.
The report as to Inventive Step was negative (NO) with respect to claims 1-11, 13-17, 19-27, 30-34, 36-38, 40, 42-43, 45, 47-49.
The report as to Industrial Applicability was positive (YES) with respect to claims 1-58.
The report as to Industrial Applicability was negative (NO) with respect to claims NONE.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
support and cushion the user.

Claim 16, Peters discloses in column 9 lines 14-19 that the geometric shapes can be triangular or rectangular, a regular polygon.

Claims 17 and 21, Peters discloses in columns 8 and 9 lines 65-68, and 9 a padding having channels on the outer wall of the pad and allows the lip around the shell and pad seals the pouch such that air is trapped between the pad and shell, creating a bladder with an air cushion.

Claim 22, see the above rejection of claim 15, and column 8 lines 40-50 disclose the pad is molded directly to shell. The pad has other supportive geometrical shapes to cushion and support the leg.

Claim 23, see above rejection of claims 9-10.

Claim 45, Peters discloses in Fig. 5 a flexible, molded outer shell (64) and at least one auxiliary member (8) comprising a material that is relatively stiffer than the outer shell, the support having a first mode in which the auxiliary member is removably secured to the outer shell to stiffen the support, and a second mode in which the member is removed from the support to make the support more flexible relative to the first mode.

Claim 42, see the above rejection of claim 45. The indentation is a one of the bubbles and the insert is the auxiliary member. The indentation (one of the bubbles) is in the outer shell (64).

Claims 5, 11, and 47-49 lack novelty under PCT Article 33(2) as being anticipated by Adams (5,007,111).

Claims 5 and 11, Adams discloses in Figs. 1-2B, and 6-11 in column 3 lines 42-59, in column , lines 1-3 and 21-36, and in column 7 lines 21-68 an orthopedic support comprising an outer shell, a molded pad bonded to shell, the pad having a surface and a plurality of molded structures to provide differing levels of cushioning support for the wearer, at least some of the

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

structures having different dimensions than others of the structures. The pad further discloses a plurality of fingers extending from the pad to the outer shell forming a fluid filled bladder and some of the fingers have a different length than others of the fingers.

Claim 47, Adams discloses in the sections described above an outer shell formed for fitting about the lower leg of the wearer, a molded pad bonded to the shell, the pad having a plurality of molded structures in between the pad and the shell to provide cushioning for the wearer. Adams discloses in column 5, lines 53-68 that the molded structure is made of a resilient material and thus can provide cushioning support for anatomy without inflating or filling the structures.

Claim 48, see the above rejection of claims 5, 11 and 47.

Claim 49, Adams discloses in Figures 1-2A and in column 6, lines 21-31 the molded pad bonded to the shell, the pad having a substantially continuous surface and having a plurality of molded structures to provide differing levels of cushioning support for the wearer and adapted to be placed against a portion of the anatomy to be supported.

Claim 24 lacks novelty under PCT Article 33(2) as being anticipated by Adams (5,007,111). Adams discloses in Figs. 16 and 17, and in column 7 lines 12-24 an orthopedic support comprising a substantially rigid shell (30), and injection molded pad (34) being integrally molded in a single molded step.

Claims 6-8 and 20 lack an inventive step under PCT Article 33(3) as being obvious over Peters in view of Grim (4,977,891). Peters discloses all the elements recited in claim 1. However, Peters does not disclose an inner liner of cloth secured to the pad on the surface of the pad facing the lower leg. Grim teaches in Fig. 6 and in column 4 lines 57-66 that it is known in the art to include an inner liner of cloth secured to and integrated with the pad on the surface of the pad for the comfort of the user. In addition, openings (96) are included in the liner to provide comfort to the user. It would have been obvious to one skilled in the art to include an inner liner in order to provide comfort to the user.

Claim 20, Grim teaches that the pad can comprise further of a foam pad to provide more support and padding. At the time of the invention, it would have been obvious to one skilled in the art to include a foam pad with the pad to provide more support and padding.

Claim 19 lacks an inventive step under PCT Article 33(3) as being obvious over Peters in view of Berguer et al. (5,403,265). Peters, as stated above, discloses all the elements recited in claim 17. However, Peters does not disclose an inlet and outlet valve for allowing entry and removal or air. Berguer et al. teach in Fig. 1, and in column 2 lines 43-464 that it is known in the orthopaedic foot art to include an inlet (30) and outlet valve (52) to control the amount of pressure in the support. It would have been obvious to one skilled in the art to include valves in Peters in order to control the pressure in the support better.

Claims 25-27, 31-33 and 36-38 lack an inventive step under PCT Article 33(3) as being obvious over Davis et al. (5,288,286) in view of Grim. Davis discloses in Figures 1-5 an orthopaedic support that includes a molded pad (20) for cushioning, wherein the pad includes interconnected cells and a heel bladder fluidics coupled to the pad for varying the pressure exerted by the pad on the limb of the user. However, Davis does not disclose substantially rigid shell or the pad being injection molded. Grim discloses in column 3, lines 14-18 that it is known in the art to include a rigid shell on an orthopaedic support f or provide support to the user. In addition, it is known to make pad by an injection molding process for cost effectiveness. It would have been obvious to one skilled in the art to include a rigid support for addition support to the user during use.

Claim 26, Davis et al. disclose the pad is a bladder having geometrically shaped cells to provide differing levels of cushioning.

Claim 27, Davis et al. disclose fluid inlets and outlets (36)(48)(80) to allow entry and removal of fluids.

Claim 28, Davis et al. disclose in column 3 lines 38-47 that the bladder defines three separate bladders or at least one cell defining a closed space forming an internal bladder.

Claim 31, Davis et al. disclose that the pad includes a plurality of integrally molded fingers (some of the bladders) extending from the pad to the shell.

Claim 32, Grim et al. disclose in Figs. 9-11 that the pad forms an over-mold molded to the shell. It would have been obvious to one skilled in the art to place the pad on the shell in various arrangements, including forming an over- mold molded to the shell.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Claim 33, see the above rejection of claims 25 and 27. It would have been obvious to one skilled in the art to attach the pad to the shell by numerous methods, including bonding, as Grim et al. teach in column 7 line 20.

Claim 36, see above rejection of claim 31.

Claim 37, see above rejection of claim 32.

Claim 38, see above rejection of claim 33 regarding bonding.

Claims 30, 34 and 40 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph, and further in view of Grim (4,977,891). See the above rejection of claim 6.

Claim 34, Grim teaches in column 4 lines 57-66 that some inflatable bladders include foam for additional cushioning.

Claim 40, Grim teaches in column 4 lines 49-56 that some bladders include air holes to provide a bleed function that may not be accomplished through a relief valve.

Claim 43 lacks an inventive step under PCT Article 33(3) as being obvious over Peters. Peters discloses that the insert and outer shell are adapted such that they are securable into the indentation using a hook and loop fastener. It is known in the art to attach pads to shells in numerous ways, including using a snap. A snap is adapted to secure into a indentation by a snap-fit. It would have been obvious to adapt the insert to secure the shell in numerous ways, including using a snap fit.

Claims 12, 18, 28, 29, 35, 39, 41, 44, 46 and 50-58 meet the criteria set out in PCT Article 33(2)-(4) because the prior art does not teach or fairly suggest the elements recited in these claims, such as fingers of greater length in the malleolar region, channels that allow for water to pass, a shell with a removable shell core, an over-mold forming a ridge, and interchangeable auxiliary members of different stiffness.

Claim 1-58 have industrial applicability because this apparatus can be used in orthopaedics to support an injured leg.

---------- NEW CITATIONS ----------
NONE

CLAIMS

WE CLAIM:

1. An orthopaedic support for comfortably supporting the ankle of a wearer, comprising:

an outer shell formed for fitting about the lower leg of the wearer;

a molded pad bonded to said shell;

said pad having a surface; and

said pad having a plurality of molded substantially hollow structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, at least some of said structures having a different dimension than others of said structures;

wherein said molded structures comprise walls, said walls providing cushioning support for the ankle even without inflating or otherwise filling said molded structures with air, liquid, gel and the like.

2. An orthopaedic support in accordance with 1 wherein an overmold substantially surrounds said pad and said shell substantially sealing together said orthopaedic support.

3. An orthopedic support as defined in claim 1 further comprising an overmold molded onto said shell, said pad being bonded to said overmold.

4. An orthopaedic support as defined in claim 1 further comprising means for securing said ankle support around the lower leg; and a heel strap for securing said orthopaedic support.

5. An orthopaedic support as defined in claim 1 wherein said pad bonded to said shell forms a fluid-filled bladder.

6. An orthopaedic support as defined in claim 1 wherein an inner liner of cloth is secured to said pad on the surface of said pad facing the lower leg of the user.

7. An orthopaedic support as defined in claim 6 wherein said liner is integrated with said pad.

8. An orthopaedic support in accordance with claim 7 wherein said liner includes openings allowing air to pass in and out of said structures.

9. An orthopaedic support as defined in claim 1, wherein said pad further comprises a plurality of fingers extending from said pad to said outer shell.

10. An orthopaedic support as defined in claim 9, wherein said fingers are integrally molded with said pad.

11. An orthopaedic support as defined in claim 9, wherein some of said fingers have a different length than others of said fingers.

12. An orthopaedic support as defined in claim 11, wherein said support has a malleolar region that is adapted to be placed against a malleolus of an ankle, said malleolar region having fingers of a greater length than fingers in other regions of said support.

13. An orthopaedic support for comfortably supporting a select area of the anatomy, said support comprising:

a substantially rigid shell; and

an injection molded resilient pad between said shell and the anatomy of the user, said pad configured with geometric shaped cells providing cushioning and support;

wherein said cells comprise walls, the structure of said walls providing cushioning support for the select area of the anatomy even without inflating the cells with air or otherwise filling said cells with liquid, gel and the like.

14. An orthopaedic support as defined in claim 13 further comprising an overmold molded onto said shell, said pad being connected to said overmold.

15. An orthopaedic support as defined in claim 13 wherein said pad is a bladder having a plurality of cells having cushioning geometric shapes and protrusions, each

cell with predetermined size, depth, and wall thickness providing varying levels of localized support and cushion in different areas of said support.

16. An orthopaedic support as defined in claim 15 wherein said geometric shapes for said bladder are selected from the group consisting of ribs, cylinders, honeycomb, and regular and irregular polygons.

17. An orthopaedic support as defined in claim 15 wherein channels are provided between said cells for allowing a fluid to pass between and among said cells, creating a massaging effect on the ankle and promoting blood flow.

18. An orthopaedic support as defined in claim 17 wherein channels are provided through an outer wall of said pad to at least one of said cells to allow water to pass between and among said cells for hot and cold therapies.

19. An orthopaedic support as defined in claim 17 wherein said support further comprises inlet and outlet valves for allowing entry and removal of air and liquids.

20. An orthopaedic support as defined in claim 13 wherein said pad further comprises a foam core for softer inner cushion.

21. An orthopaedic support as defined in claim 13 wherein a co-molded lip around said shell and around said pad seals said pad such that air is trapped between said pad and said shell, creating a bladder with air cushion.

22. An orthopaedic support as defined in claim 13 wherein said pad is molded directly onto said shell as channels, domes, and other supportive geometrical shapes to cushion and to support the anatomy.

23. An orthopadic support as defined in claim 13 wherein said pad includes a plurality of fingers extending from said pad to said shell.

24. An orthopaedic support comprising:

a substantially rigid shell formed to fit a limb of a user;

an injection molded pad for cushioning the shell to the limb;

said injection molded pad being integrally molded in a single molding step.

25. An orthopaedic support as defined in claim 24 wherein said pad includes interconnected cells, and further comprising a heel bladder fluidically coupled to said pad for varying the pressure exerted by said pad on the limb of the user.

26. An orthopaedic support pad as defined in claim 24 wherein said pad is a bladder having geometrically shaped cells to provide differing levels of localized cushioning and a plurality of channels molded between said cells to allow air and fluid to pass between said cells.

27. An orthopaedic support pad as defined in claim 26 further comprising fluid inlets and outlets to allow entry and removal of fluid from said pad for hot and cold therapy.

28. An orthopaedic support as defined in claim 26 wherein at least one cell defines a closed space forming an internal bladder.

29. An orthopaedic support as defined in claim 24 wherein said shell further comprises a shell frame and a shell core which is removably mounted within said shell.

30. An orthopaedic support as defined in claim 24 wherein a breathable liner covers said pad.

31. An orthopadic support as defined in claim 24 wherein said pad includes a plurality of integrally-molded fingers extending from said pad to said shell.

32. An orthopaedic support as defined in claim 24 further comprising an overmold molded onto said shell.

33. An orthopaedic support for comfortably supporting the ankle comprising:

an ankle support formed for fitting about the lower leg, having appropriate configuration to support the ankle;

said ankle support comprising a substantially rigid outer shell and a molded pad for cushioning;

said pad having an inner surface and an outer layer, said inner surface including resilient material having cells therein for providing resilient support to the ankle; and

said pad being bonded to said outer shell;

wherein said outer shell has at least one opening to allow air to escape from space in between said outer shell and said pad, said cells providing resilient support to the ankle from the structure of the cells even without being filled with air, liquid, gel and the like.

34. An orthopaedic support as defined in claim 33 wherein at least some of said air spaces are filled with foam for cushioning.

35. An orthopaedic support as defined in claim 34 wherein said foam surrounds but not covers the malleolus.

36. An orthopaedic support as defined in claim 33 wherein said pad includes a plurality of fingers extending from said pad toward said shell.

37. An orthopaedic support as defined in claim 33 further comprising an overmold molded onto said shell.

38. An orthopaedic support as defined in claim 37 wherein said pad is bonded to said overmold.

39. An orthopaedic support as defined in claim 38 wherein said overmold includes a ridge extending about the periphery of the overmold, said pad having an outer edge that engages with said ridge.

40. An orthopaedic support as defined in claim 33 wherein said pad includes a plurality of air holes to prevent formation of a bladder between said pad and said shell.

41. An orthopaedic support as defined in claim 33 wherein said pad has a non-uniform skin thickness, said pad having at least one region having skin that is thicker than at least one other region, in order to improve the function of the support.

42. An orthopaedic support comprising:

a flexible, molded outer shell having a first surface and a second surface, said first surface having an indentation therein; and at least one insert comprising a material that is relatively stiffer than said outer shell;

said support having a first mode in which said insert is removably secured within said indentation in said outer shell to stiffen the support, and a second mode in which said insert is removed from said indentation in said outer shell to make said support more flexible relative to said first mode.

43. An orthopaedic support as defined in claim 42, wherein said insert and said outer shell are adapted such that said insert is securable into the indentation in said outer shell by snap fit.

44. An orthopaedic support as defined in claim 42 further comprising a molded pad bonded to said shell, said pad having a substantially continuous surface and having a plurality of molded structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, said substantially continuous surface of said pad being adapted to be placed against a portion of the anatomy to be supported.

45. An orthopaedic support comprising:

a flexible, molded outer shell; and

at least one auxiliary member comprising a material that is relatively stiffer than said outer shell;

said support having a first mode in which said auxiliary member is removably secured to said outer shell to stiffen the support, and a second mode in which said insert is removed from said support to make said support more flexible relative to said first mode.

46. An orthopaedic support as defined in claim 45 further comprising a plurality of different interchangeable auxiliary members, each having a different stiffness, wherein a user may select a particular member depending on the stiffness desired.

47. An orthopaedic support for comfortably supporting the ankle of a wearer, comprising:

an outer shell formed for fitting about the lower leg of the wearer;

a molded pad bonded to said shell;

said pad having a plurality of molded structures in between said pad and said shell to provide cushioning support for the wearer;

wherein said molded structures comprise walls, the structure of said walls providing cushioning support for the select area of the anatomy without inflating said structures with air or otherwise filling said structures with liquid, gel and the like.

48. An orthopaedic support for comfortably supporting a select area of the anatomy, said support comprising:

a substantially rigid shell; and

an injection molded resilient pad between said shell and the anatomy of the user, said pad being configured with geometric shaped cells providing cushioning and support;

said pad being bonded to said shell to form a fluid-filled bladder.

49. An orthopaedic support as defined in claim 48, further comprising a molded pad bonded to said shell, said pad having a substantially continuous surface and having a plurality of molded structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, said substantially continuous surface of said pad being adapted to be placed against a portion of the anatomy to be supported.

50. An orthopaedic support for comfortably supporting the ankle of a wearer, comprising:

an outer shell formed for fitting about the lower leg of the wearer;

a molded pad bonded to said shell;

said pad having a surface; and

said pad having a plurality of molded structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, at least some of said structures having a different dimension than others of said structures;

wherein said pad further comprises a plurality of fingers extending from said pad to said outer shell;

some of said fingers having a different length than others of said fingers; and

said support having a malleolar region that is adapted to be placed against a malleolus of an ankle, said malleolar region having fingers of a greater length than fingers in other regions of said support.

51. An orthopaedic support for comfortably supporting a select area of the anatomy, said support comprising:

a substantially rigid shell; and

an injection molded resilient pad between said shell and the anatomy of the user, said pad configured with geometric shaped cells providing cushioning and support;

wherein said pad is a bladder having a plurality of cells having cushioning geometric shapes and protrusions, each cell with predetermined size, depth, and wall thickness providing varying levels of localized support and cushion in different areas of said support;

wherein channels are provided between said cells for allowing a fluid to pass between and among said cells, creating a massaging effect on the ankle and promoting blood flow; and

wherein channels are provided through an outer wall of said pad to at least one of said cells for allowing a fluid to flow into said pad for hot and cold therapies.

52. An orthopaedic support comprising:

a substantially rigid shell formed to fit a limb of a user;

an injection molded pad for cushioning the shell to the limb;

said injection molded pad being integrally molded in a single molding step;

wherein said pad is a bladder having geometrically shaped cells to provide differing levels of localized cushioning and a plurality of channels molded between said cells to allow air and fluid to pass between said cells;

wherein at least one cell defines a closed space forming an internal bladder.

53. An orthopaedic support comprising:

a substantially rigid shell formed to fit a limb of a user;

an injection molded pad for cushioning the shell to the limb;

said injection molded pad being integrally molded in a single molding step;

wherein said shell further comprises a shell frame and a shell core which is removably mounted within said shell.

54. An orthopaedic support for comfortably supporting the ankle comprising:

an ankle support formed for fitting about the lower leg, having appropriate configuration to support the ankle;

said ankle support comprising a substantially rigid outer shell and a molded pad for cushioning;

said pad having an inner surface and an outer layer, said inner surface including resilient material having cells therein for providing resilient support to the ankle; and

said pad being bonded to said outer shell;

wherein said outer shell has at least one opening to allow air to escape from space in between said outer shell and said pad, said cells providing resilient support to the ankle from the structure of the cells even without being filled with air;

wherein at least some of said air spaces are filled with foam for cushioning; and

wherein said foam surrounds but not covers the malleolus.

55. An orthopaedic support for comfortably supporting the ankle comprising:

an ankle support formed for fitting about the lower leg, having appropriate configuration to support the ankle;

said ankle support comprising a substantially rigid outer shell and a molded pad for cushioning;

said pad having an inner surface and an outer layer, said inner surface including resilient material having cells therein for providing resilient support to the ankle; and

said pad being bonded to said outer shell;

wherein said outer shell has at least one opening to allow air to escape from space in between said outer shell and said pad, said cells providing resilient support to the ankle from the structure of the cells even without being filled with air;

wherein said orthopaedic support further comprises an overmold molded onto said shell;

wherein said pad is bonded to said overmold; and

wherein said overmold includes a ridge extending about the periphery of the overmold, said pad having an outer edge that engages with said ridge.

56. An orthopaedic support for comfortably supporting the ankle comprising:

an ankle support formed for fitting about the lower leg, having appropriate configuration to support the ankle;.

said ankle support comprising a substantially rigid outer shell and a molded pad for cushioning;

said pad having an inner surface and an outer layer, said inner surface including resilient material having cells therein for providing resilient support to the ankle; and

said pad being bonded to said outer shell;

wherein said outer shell has at least one opening to allow air to escape from space in between said outer shell and said pad, said cells providing resilient support to the ankle from the structure of the cells even without being filled with air; and

wherein said pad has a non-uniform skin thickness, said pad having at least one region having skin that is thicker than at least one other region, in order to improve the function of the support.

57. An orthopaedic support comprising:

a flexible, molded outer shell having a first surface and a second surface, said first surface having an indentation therein; and at least one insert comprising a material that is relatively stiffer than said outer shell;

said support having a first mode in which said insert is removably secured within said indentation to stiffen the support, and a second mode in which said insert is removed from said indentation to make said support more flexible relative to said first mode;

wherein said orthopaedic support further comprises a molded pad bonded to said shell, said pad having a substantially continuous surface and having a plurality of molded structures to provide differing levels of cushioning support for the wearer of the orthopaedic support at different areas of the pad, said substantially continuous surface of said pad being adapted to be placed against a portion of the anatomy to be supported.

58. An orthopaedic support comprising:

a flexible, molded outer shell; and

a plurality of different interchangeable auxiliary members, at least one of said auxiliary members comprising a material that is relatively stiffer than said outer shell;

said support having a first mode in which at least one of said auxiliary member is removably secured to said outer shell to stiffen the support, and a second mode in which said at least one insert is removed from said support to make said support more flexible relative to said first mode;

wherein a user may select a particular member depending on the stiffness desired.